PB88-174412

Guidance for the Reregistration of Pesticide Products Containing Phosphamidon as the Active Ingredient of Pesticide Programs

(U.S.) Environmental Protection Agency
Washington, DC

Dec 87

U.S. Department of Commerce
National Technical Information Service
NTIS

PB88-174412

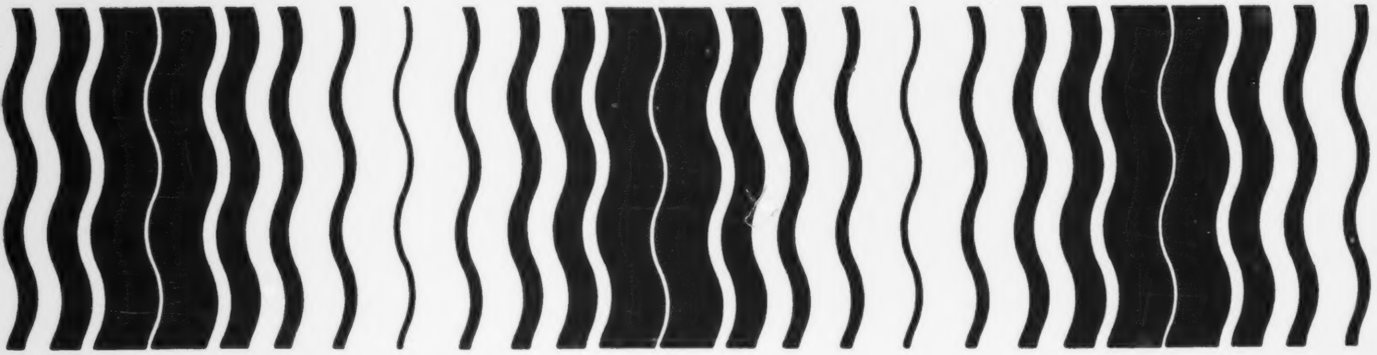
United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

December 1987

Pesticides

Guidance for the Reregistration of Pesticide Products Containing Phosphamidon as the Active Ingredient



REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires 11/89

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PHOSPHAMIDON
(018201)

AS THE ACTIVE INGREDIENT

Case Number 157

CAS 13171-21-6 [(E-+(Z)-isomers]
CAS 23783-98-4 [(Z)-isomer]
CAS 297-99-4 [(E)-isomer]

December 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C.

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2. PB88

3. Recipient's Accession No. 8 174412/AS

4. Title and Subtitle

Guidance for the Registration of Pesticide Products Containing PHOSPHAMIDON as the Active Ingredient

5. Report Date DECEMBER 1987

6.

7. Author(s)

EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No. 540/RS-88- 034

9. Performing Organization Name and Address

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, SW
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 141

22. Price PC06 19.95 / MF 6.95

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

TABLE OF CONTENTS

I. Introduction 1

II. Chemical(s) Covered by this Standard 4
  A. Description of Chemical
  B. Use Profile
  C. Registration History

III. Agency Assessment 7
  A. Summary Science Findings
  B. Summary of Data Gaps
  C. Preliminary Health Risk Assessment
  D. Environmental Profile
  E. Tolerance Reassessment

IV. Regulatory Position and Rationale 23
  A. Regulatory Positions
  B. Criteria for Registration
  C. Acceptable Ranges and Limits
  D. Labeling

V. Products Subject to this Standard 33

VI. Requirement for Submission of Generic Data 35
  A. What are generic data?
  B. Who must submit generic data?
  C. What generic data must be submitted?
  D. How to comply with DCI requirements
  E. Procedures for requesting a change in protocol
  F. Procedures for requesting extensions of time
  G. Existing stocks provisions uipon suspension or cancellation

VII. Requirement for Submission of Product-Specific Data . . 41

VIII. Requirement for Submission of Revised Labeling 42

IX. Instructions for Submission 42
  A. Manufacturing use products (sole active)
  B. Manufacturing use products (multiple active)
  C. End use products
  D. Intrastate products
  E. Addresses

APPENDICES

I. DATA APPENDICES

Guide to Tables

Table A

Table B

Table C (not applicable for this Standard)

II. LABELING APPENDICES

Summary of Label Requirements and Table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product-specific Data Report
EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration system in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and lableing into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produces in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review, EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of a conclusion from available data in its files pertaining to the pesticide active ingredient (a.i.). However, during the review of these data, the Agency is also looking for potential hazards that may be associated with the end-use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end-use products if necessary to protect man and the environment.

---

[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M Street SW., Washington, DC 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses (See Section IV - Regulatory Position and Rationale). Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially-trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Canel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provision of FIFRA section 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA section 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common Name: Phosphamidon

Chemical Name: 2-chloro-3-(diethylamino)-1-methyl-3-oxo-1-propenyl dimethyl phosphate

Other Chemical Nomenclature: dimethyl phosphate ester 2-chloro-*N*,*N*-diethyl-3-hydroxycrotonamide;

2-chloro-2-diethylcarbamoyl-1-methylvinyl dimethyl phosphate;

O,O-dimethyl-O-(2-chloro-2-diethylcarbamoyl-1-methylvinyl) phosphate

Trade Names: Apamidon; C570; Ciba 570; Dimecron; Dixon; Dimenox

Chemical Class: Organophosphate

Empirical Formula: $C_{10}H_{19}ClNO_5P$

CAS Registry Nos.: 13171-21-6 [(E)-+(Z)-isomers]
23783-98-4 [(Z)-isomer]
297-99-4 [(E)-isomer]

Shaughnessy No.: 018201

Physical/chemical properties of pure phosphamidon and of the technical phosphamidon.

Color: Colorless (PAI*),
Slightly amber oil (T*)

Physical State: Liquid (PAI)

Odor: Odorless, faint, mild (PAI)

Melting Point: Liquid at room temperature

---

*PAI = Pure Active Ingredient, T = Technical

Boiling Point: 160 °C, 1.5 mm (PAI)

Density: 1.2 at 20 °C (PAI)

Solubility: Miscible with water, alcohol, and ketones. Highly soluble in aromatic and chlorinated hydrocarbons, esters and ethers. Solubility in hexane is 3.23 g/100 g 25°C (PAI)

Vapor Pressure: 2.5 x 10^{-5} mm Hg at 20 °C (PAI)

Octanol/Water Partition Coefficient: Log P = 0.8 (PAI)

Stability in water: Half-life at 2 ppm and 38 °C is 70 hours at pH 9.1 and > 300 hours at pH 1.1 (PAI).

Half-life (in days) of phosphamidon in buffered media (T):

	Temperature	
pH	23 °C	45 °C
4	74	6.6
7	13.8	2.1
10	2.2	0.14

B. Use Profile

Phosphamidon is a systemic organophosphate insecticide/ acaricide registered for use to control many insects, primarily aphids, leafminers, and mites. Registered sites include a variety of field, fruit and vegetable crops, with the predominate uses on apples, potatoes, walnuts and tomatoes.

Usage information indicates that about two-thirds of the phosphamidon used in the United States is applied to apples. The second major use, approximately one-fifth, is on potatoes, with walnuts third, and in decreasing volume, tomatoes, cauliflower, and broccoli. Other uses account for less than 0.3 percent individually.

Phosphamidon is marketed as an 8 lb ai/gal SC/L (soluble concentrate/liquid), and is formulated from a single 89.5% technical product. Phosphamidon is applied by ground and aerial application.

C. Registration History

Phosphamidon was first registered for use in the U.S. in 1963 by Ciba-Geigy as a 89.5% technical product. It exists as a mixture of 70% (Z) isomer (beta isomer) and 30% E (alpha isomer). The Z isomer is the most active insecticidally. There are nine federally registered products (1 technical and 8 end-use products), two Special Local Need [FIFRA §24(c)] registrations, and five intrastate registrations containing phosphamidon as a single active ingredient.

The Agency has classified all phosphamidon end-use liquid formulations of 75% and greater and all dust formulations 1.5% and greater as Restricted Use pesticides, based on acute dermal toxicity and residue effects on mammalian and avian species. However, no dust formulation products are currently registered.

The Agency has issued three Data Call-in Notices (DCIs) under FIFRA §3(c)(2)(B) on phosphamidon. In September 1981, EPA issued a combined DCI which was a result of the Agency's ongoing DCI Program for chronic data (chronic feeding, reproduction, and teratogenicity). The second DCI was issued in May 1984 for environmental fate data (hydrolysis, photodegradation in water and soil; aerobic soil metabolism, anaerobic aquatic metabolism, mobility, field dissipation) and product chemistry data (water solubility, octanol/water partition coefficient). The third DCI was issued in February 1985 for foliar and soil dissipation data, and dermal and inhalation exposure studies.

The registrant has submitted data in response to the DCI Notices of September 1981 and May 1984. Soil dissipation and foliar dislodgeable residue studies requested in the February, 1985 DCI have been submitted. The dermal and inhalation exposure studies required under this DCI have been waived.

III. AGENCY ASSESSMENT

A. SUMMARY SCIENCE FINDINGS

1. Toxicology

The following is a summary of scientific findings based on the available toxicity data on phosphamidon:

Acute Effects

The Agency has no valid acute toxicity studies for phosphamidon. All of the acute toxicity studies are therefore required.

Subchronic Effects

The Agency has no valid subchronic studies for phosphamidon. However, since a valid 2-year rat feeding study is available, a subchronic oral toxicity study in a rodent species is not required. A subchronic oral toxicity study in a nonrodent species and a subchronic 21-day dermal study are required.

Chronic Effects

A 2-year rat feeding study showed toxic signs of cholinesterase inhibition activity in serum and brain, decreased body weights, erythrocyte counts, hemoglobin levels and necrotic changes in the stomach and other organs. A NOEL for chronic toxicity in rats was 1.0 ppm (0.05 mg/kg/day) and the LEL was 30 ppm (1.5 mg/kg/day). Studies on the toxic effects of phosphamidon in nonrodent species are not available. A 1-year feeding study in a nonrodent species is required.

Oncogenicity

The available oncogenicity studies for phosphamidon include a rat oncogenic study (the 2-year rat feeding study is considered to be an acceptable oncogenic study) and National Cancer Institute (NCI) bioassays with rats and mice. The NCI mouse and rat bioassays were not conducted in accordance with the guideline requirements for an oncogenicity study and are therefore not adequate to satisfy the mouse onocogenicity data requirement. An oncogenicity study in the mouse is required.

Developmental Effects (Teratogenicity)

Sufficient data are available that allows the Agency to conclude that phosphamidon did not demonstrate any significant developmental toxic effects in the rat and rabbit. No additional data are required.

Reproduction

Based upon a 2-generation rat reproduction study, the parental NOEL was shown to be 30 ppm (1.5 mg/kg/day) and the reproductive/developmental NOEL as 5 ppm (0.25 mg/kg/day). Additional data are not required.

Mutagenicity

No data are available to evaluate the mutagenic potential of phosphamidon. Gene mutation, chromosomal aberration, and direct DNA damage studies are required.

Metabolism

No data on the metabolic pathway of phosphamidon are available. A metabolism study is required.

Worker Exposure

The use of phosphamidon poses risks to mixers, loaders, applicators, and persons reentering treated fields. Exposure may be by dermal, inhalation, and ocular routes of entry. Federally registered end-use phosphamidon products do not currently have any reentry restrictions or require protective clothing. The Agency is specifying label language which requires the use of protective clothing and imposes an interim 48-hour reentry interval until required data are reviewed, evaluated and the Agency announces any change in its position.

2. Ecological Effects

The following is a summary of scientific findings based on the available ecological effects data on phosphamidon.

Avian Species

Phosphamidon is acutely and subacutely very highly toxic to a variety of avian species and can be lethal to birds through dermal exposure. Avian reproduction and field studies are required to assess the effect on nontarget organisms. In addition, available information indicate that delayed mortality of birds occurs after applications of phosphamidon (in some cases up to several weeks). Since available information suggests that phosphamidon may have a relatively short half-life, it follows that some degradate of phosphamidon may be a bird toxicant. Acute and subacute studies on each major degradate of phosphamidon are required.

Aquatic Organisms

Based upon the available fish and wildlife data, technical phosphamidon is very highly toxic to both coldwater and warmwater fish species, aquatic invertebrates, and mammals. Additional data are required to assess the potential impact on aquatic organisms.

Nontarget Insects

Available data indicate that phosphamidon is highly toxic to honey bees, predaceous mites, parasitic wasps, and predaceous beetles. Additional data are not required under this Standard.

Endangered Species Considerations

The Agency has evaluated the risk phosphamidon poses to endangered species and the previously issued biological opinions prepared by the Department of the Interior's Office of Endangered Species (OES) for pesticides used on apples, citrus and other fruits, vegetables, and cotton. Based on the Agency's evaluation, it appears that phosphamidon use on apples, citrus and other fruits and vegetables, and cotton may result in sufficient exposure to pose a potential hazard to certain endangered species of mammals, birds, aquatic invertebrates, insects, reptiles, and plants (based on the loss of pollinators). Refer to PR Notice 87-5 for endangered species labeling for the use of phosphamidon on cotton. Based on jeopardy opinions received for pesticides having similar use patterns, assumptions of jeopardy have been made for additional non-target species for various fruit and vegetable uses of phosphamidon. Should the Office of Endangered Species concur in an assumption of jeopardy, appropriate labeling will be required.

3. Environmental Fate

Available environmental fate data on phosphamidon are insufficient to fully assess the environmental fate of and the exposure of humans and nontarget organisms to phosphamidon, including the extent of groundwater contamination, phosphamidon persistence in the environment, and the need for crop rotational label restrictions.

4. Tolerance Reassessment

Because of extensive residue chemistry and toxicology data gaps, the Agency cannot complete a tolerance reassessment.

B. SUMMARY OF DATA GAPS:

The Agency has identified missing data necessary for use in evaluating the human and environmental risks associated with the use of phosphamidon. A summary of those data gaps is given below. Please note, this is only a summary and complete details can be obtained by referring to the data tables in Appendix I. These data must be developed and submitted in order to maintain registrations of existing products or to register any new products containing phosphamidon.

Toxicology

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Primary Eye Irritation
- Primary Dermal Irritation
- Dermal Sensitization
- Acute Delayed Neurotoxicity (Hen)
- Subchronic 90-day feeding (nonrodent)*
- Subchronic 21-Day Dermal
- Chronic Toxicity (nonrodent)
- Oncogenicity (mouse)
- Mutagenicity (Gene Mutation, Chromosomal Aberration and Direct DNA Damage and Repair Studies)
- Metabolism (rats)

Environmental Fate/Exposure

- Hydrolysis
- Photodegradation
  - In water
  - In soil
  - In air
- Metabolism
  - Aerobic Soil
  - Anaerobic Soil
- Mobility
  - Leaching and Adsorption/Desorption
  - Laboratory Volatility
  - Field Volatility
- Dissipation Studies - Field
  - Soil Dissipation
  - Confined Accumulation Study
  - Fish Accumulation Study
- Reentry Protection
  - Foliar Dissipation
- Spray Drift
  - Droplet Size Spectrum
  - Drift Field Evaluation

Ecological Effects

- Acute Avian Oral Toxicity (Degradate)
- Acute Avian Dietary Toxicity (Degradate)
- Avian Reproduction
- Avian Field Testing (Mammals, Birds)
- Special Avian Testing (Dermal Toxicity)
- Acute Toxicity to Estuarine and Marine Organisms
- Fish Early Life Stage and Aquatic Invertebrate Life Cycle
- Aquatic Residue Monitoring

---

* Not required if an acceptable chronic study is submitted.

Residue Chemistry

Nature of Residues (Plants, Livestock)
Residue Analytical Method (Plant, Animal)
Storage Stability
Magnitude of Residues (Field Crop)

Product Chemistry

All product chemistry studies

C. PRELIMINARY HEALTH RISK ASSESSMENT

Numerous data gaps exist for phosphamidon and few definitive conclusions can be made pending receipt of additional data. The following preliminary health risk assessment is based on the data available.

1. Acute Toxicity

There are no acute toxicology studies available for technical phosphamidon. Phosphamidon is an organophosphate insecticide whose primary mechanism of action is an inhibition of cholinesterase activity. Technical phosphamidon is currently labeled as a Toxicity Category I pesticide. A precautionary statement on the label states that phosphamidon is "Rapidly absorbed through skin". The lack of acute toxicity studies precludes the Agency from determining at this time the acute toxic effects or from refining further the toxicity category for this product. Therefore, the currently assigned Toxicity Category I will be retained until acute data for phosphamidon are received and evaluated.

2. Subchronic Toxicity

There are no subchronic feeding data *per se* available. However, these data requirements may be satisfied with adequate chronic feeding studies. Subchronic dermal (90-day) and subchronic inhalation studies are not required at this time since the Agency has determined that the existing acceptable end-uses of phosphamidon should not result in repeated human skin contact for extended periods or repeated inhalation exposure. The requirement for a subchronic neurotoxicity study is reserved pending the results of the required acute neurotoxicity study. A subchronic dermal (21-day) study is required.

3. Chronic Toxicity

The only chronic feeding study available to the Agency is a 2-year rat feeding study. In this study Sprague-Dawley rats (60 animals/sex/dose level) were fed diets containing 0, 1.0, 30.0, or 80.0 parts per million (ppm) of technical grade phosphamidon for a two (2) year period. The findings observed in the low-dose group (1.0 ppm) were generally similar to those of the controls. In the mid-dose (30.0 ppm) and high-dose (80.0 ppm) groups the statistically significant ($p \leq 0.05$ to 0.01) findings included the inhibition of cholinesterase activity in brain and serum, and toxic signs (muscle tremors, irritability) associated with the cholinesterase inhibition activity· decreased body weights, erythrocyte counts, hemoglobin levels and hematocrit values, and increased leucocyte and platelet counts; increased number of animals with Howell-Jolly bodies in erythrocytes; increased incidence of ulcerated, thickened, or swollen footpads and hyperkeratotic dermatitis in the tail, accompanied by degenerative changes in the draining lymph nodes and inflammation at distal sites; increased incidence of hepatocellular degeneration/necrosis, mucosal erosion and hyperplasia of the stomach (high-dose males); peribronchial inflammatory infiltration/nodules and pneumonitis (high-dose males); peribronchial pneumonia (high-dose females); and increased incidence of ophthalmologic findings (cataracts, subcapsular opacity, and atrophy of the iris) in the high-dose groups.

The No Observed Effect Level (NOEL) for chronic toxicity in rats was 1.0 ppm (0.05 mg/kg/day) and the Lowest Effect Level (LEL) was 30.0 ppm (1.5 mg/kg/day) for the cholinesterase inhibiting effect.

Studies on the effects of phosphamidon on a nonrodent species are not available. A 1-year feeding study in a nonrodent species is required.

4. Oncogenicity

The available oncogenicity studies for phosphamidon include a rat oncogenic study (the 2-year rat feeding study presented above under Chronic Toxicity is considered to be an acceptable oncogenic study) and National Cancer Institute (NCI) bioassays with rats and mice. The NCI mouse and rat bioassays were not conducted in accordance with the guideline requirements for an oncogenicity study and are therefore not adequate to satisfy the mouse onocogenicity data requirement. An oncogenicity study in the mouse is required.

In the rat oncogenicity study, Sprague-Dawley rats were orally dosed at 0, 1.0, 30.0 or 80.0 ppm of technical grade phosphamidon for 2 years. As discused above under Chronic Toxicity, several toxic signs and mortality were observed and it appeared that the maximum tolerated dose (MTD) was reached.

In the male rats, there was an increased incidence of transitional cell carcinoma in the bladder, adrenal cortical adenoma, and hepatocellular carcinoma when the treated animals were compared with the controls. In the female rats, there was a dose-related increased incidence of granulosa-theca cell tumor in the ovary. The incidence* of these neoplasms was as follows:

Phosphamidon (ppm)	0	1.0	30.0	80.0
Bladder: Transitional cell carcinoma	0	0	1/68 (1.5)	3/77 (3.9)
Adrenal: Cortical adenoma	1/80 (1.2)	3/70 (4.3)	3/70 (4.3)	5/79 (6.3)
Liver: Hepatocellular carcinoma	1/80 (1.2)	1/68 (1.5)	5/70 (7.1)	5/80 (6.2)
Hepatocellular adenoma	2/80 (2.5)	2/68 (2.9)	3/70 (4.3)	2/80 (2.5)
Combined	3/80 (3.7)	3/68 (4.4)	8/70 (11.4)	7/80 (8.7)
Ovary: Granulosa-theca cell tumor	2/80 (2.5)	2/70 (2.9)	3/70 (4.3)	5/80 (6.2)

The Agency's preliminary statistical analysis (using the Cochran-Armitage test, not adjusted for survival) indicated that there was no statistical significance to the incidence of adrenal cortical adenoma and ovarian granulosa-theca cell tumor. However, significant trends were noted in hepatocellular carcinoma and transitional cell carcinoma of the bladder.

Because of the low incidence of the above neoplasms and the lack of a dose relationship in the case of some neoplasms, the Agency concluded that the oncogenic potential of phosphamidon could not be assessed adequately without considering the historical control data. Therefore, the Agency requested those data and they are currently undergoing Agency review.

In the NCI bioassays Osborne-Mendel rats were fed technical phosphamidon in the diet for 80 weeks and then were observed without phosphamidon administration for 30 or 31 weeks before being sacrificed. B6CF1 mice were fed diets containing phosphamidon as follows: low-dose males, 71 weeks on the phosphamidon diet and 19 weeks observation without phosphamidon administration; high-dose males, 62 weeks on the phosphamidon diet and 28 weeks observation without phosphamidon administration; low-dose and high-dose females, 80 weeks on the phosphamidon diet and 10 or 11 weeks observation without phosphamidon administration. The levels of phosphamidon fed to each species were 0, 80, and 160 ppm. Fifty males and fifty females per dose level were assigned to the treated groups, but only 10 males and 10 females were in the control groups.

No hepatocellular carcinomas were observed in the male rats in the NCI study. The incidence of cortical adenoma of the adrenal in male rats in the low-dose group (6/49) was significantly higher ($p = 0.023$) than that in the control group

---

* Incidence = Number of neoplasms observed/number of tissues examined and (percent).

(0/8) but was not significant in the high-dose group (2/49). Therefore, the occurrence of these tumors was not considered to be related to the administration of the test chemical. Transitional cell carcinoma of the bladder was observed only in one high-dose male (1/47). Single incidences of ovarian granulose cell tumor were observed in both the mid-dose (1/49) and high dose (1/49) females. No tumors occurred at a higher incidence in mice dosed with phosphamidon than in the controls.

Technical phosphamidon was not considered to be oncogenic to Osborne-Mendel rats nor to B6C3F1 mice in the NCI bioassay. However, the Agency considers these studies to be inadequate to assess the oncogenic potential of phosphamidon.

5. Developmental Effects (Teratogenicity)

The three available teratology studies (two in the rat and one in the rabbit) satisfy the teratology data requirements for phosphamidon.

In one rat study, phosphamidon was administered orally at doses of 0, 1, 2, or 4 mg/kg. A developmental NOEL of 2 mg/kg was based on significantly increased incidences of runts and fetuses with one or more malformations in the 4 mg/kg group compared to the controls. Visceral malformations were not observed in this study. The maternal NOEL was reported to be 1.0 mg/kg. It was concluded that phosphamidon did not demonstrate significant developmental toxic effects in this study. In the second rat study, phosphamidon was administered orally at doses of 0, 0.5, 2, 4 or 6 mg/kg. A developmental NOEL 2.0 mg/kg and a maternal NOEL of 0.5 mg/kg were reported. The developmental effects were attributed to maternal toxicity. No significant developmental toxic effects were observed in fetuses from treated dams.

In an acceptable rabbit (New Zealand strain) study, the animals were treated with phosphamidon technical by gavage on days 6 through 18 of gestation at doses of 0, 1, 3, or 10 mg/kg. Phosphamidon had no effect on maternal survival, clinical signs, fetotoxic effects and other parameters examined. However, rabbits treated at rates of 0, 2, 4, 8, and 12 mg/kg in a range finding study displayed maternal effects (death, hemorrhagic foci throughout the stomach) at the 12 mg/kg treatment level. Maternal toxicity was therefore established at the 10 mg/kg level, maternal NOEL at 3 mg/kg, and maternal LEL of 10 mg/kg. At this dosing level significantly reduced body weight gains during the treatment period were observed when the treated animals were compared to the controls. However, when body weights were corrected for gravid uterine weights treated animals were not significantly different from the controls. Fetal effects were not observed, and a developmental NOEL of > 10 mg/kg (HDT) was established.

Based on the data described above, it was concluded that phosphamidon did not demonstrate any significant developmental toxic effects to rats and rabbits.

6. Reproductive Effects

The available 2-generation rat reproduction study satisfies this data requirement. Additional data are not required.

In the 2-generation reproduction study in Charles River rats fed technical phosphamidon at levels of 0, 5, 30, or 50 ppm, the reproductive and developmental effects included reduced pup survival; reduced pup weights and reduced organ weight (liver, kidney, and testes) to brain weight ratios in the 30 and 50 ppm groups; and prolonged precoital intervals, reduced mating indices and reduced pregnancy rates and breeding intervals at the 50 ppm level.

This study yielded a parental NOEL of 30 ppm (1.5 mg/kg/day) and a parental LEL of 50 ppm (2.5 mg/kg/day). The reproductive/developmental NOEL was 5 ppm (0.25 mg/kg/day) and the LEL was 30 ppm (1.5 mg/kg/day).

7. Mutagenicity

No data are available to evaluate the mutagenic potential of phosphamidon. Gene mutation, chromosomal aberration, and direct DNA damage studies are required.

8. Metabolism

No data are available to evaluate the mammalian metabolism of phosphamidon. A metabolism study in the rat is required.

9. Worker Exposure

Mixers, loaders, applicators, and persons reentering treated fields may be exposed to phosphamidon. Although acute toxicity data are currently unavailable, all phosphamidon products are currently classified as Toxicity Category I. Labeling for both the manufacturing-use and end-use products state that the product is "Rapidly absorbed through skin". Since exposure may be by dermal, inhalation, and ocular routes of entry, the Agency believes that appropriate protective clothing and reentry intervals are necessary to reduce potential risks to workers exposed to phosphamidon.

Reentry data are generally required to assess hazards to farm workers resulting from reentry into pesticide treated areas. To develop a chemical specific reentry interval, studies on toxicity, residue dissipation, and human exposure are generally needed. Monitoring data generated during exposure studies are used to determine the quantity of pesticide residues to which people may be exposed after application.

In 1985 the Agency required the registrants of phosphamidon products to submit appropriate reentry studies. A foliar dissipation study in citrus and a soil dissipation study in potatoes received by the Agency are currently under review. Dermal and inhalation exposure studies are normally optional for these use patterns and have not been submitted. After the Agency's review and assessment of the submitted foliar and soil dissipation studies, a chemical specific reentry interval for all agricultural uses of phosphamidon will be established.

D. ENVIRONMENTAL PROFILE

1. Environmental Fate

Available data reviewed by the Agency are not sufficient to fulfill the data requirements. Therefore, the the environmental fate of phosphamidon cannot be fully assessed.

The available data suggest that phosphamidon is readily susceptable to hydrolysis. Reported (but unconfirmed) results indicate that hydrolysis is pH dependent with half-lives of 4 and 14-21 days at pH's of 9 and 5-7, respectively.

Phosphamidon appears to be relatively short lived in aerobic soil. A half-life of < 3 days was reported for metabolism in a silt loam soil. N,N-diethyl-2-chloroacetoacetamide and N-ethyl-2-chloroacetamide were identified as the two major nonvolatile degradates, but the characterization of degradates has not been completed. Most of the ^{14}C from 1-vinyl and carbonyl portions was evolved as $^{14}CO_2$ (79.6% in 60 days).

Phosphamidon residues are considered to be highly mobile in soil. However, the relative mobilities of the parent compound and its degradates have not been adequately defined. Freundlich absorption coefficients were determined to be 1.36 for several soils including muck soil. Both aged (32 day aerobic) and unaged residues of ^{14}C-phospamidon were readily leached (20 inches of water) from 12-inch columns of loamy sand. More than 78% of the residues from the unaged phosphamidon were recovered from the leachate; 69-74% of the residues were leached through the column in the aged study.

Available data are not adequate to fully assess the potential of phosphamidon to contaminate ground water. However, available mobility data suggests that leaching of phosphamidon residues is possible. Limited data also indicate that the parent compound is rapidly dissipated under field conditions but the fate of degradates is not fully understood. When the required data are submitted, the potential of phosphamidon and its degradates to contaminate ground water will be reassessed.

2. Spray Drift

There are no data available to assess the hazard to nontarget organisms (fish and wildlife, domestic animals, and humans) caused by drift from aerial applications of phosphamidon. Droplet size spectrum and spray drift field evaluation studies are required to assess this concern.

3. Ecological Characteristics

Avian Species

Technical phosphamidon is very highly acutely toxic to birds as demonstrated by both acute and dietary studies.

Acute oral toxicity tests with birds resulted in acute toxicity values ranging from 1.5 mg/kg (sharp-tailed grouse) to 11.8 mg/kg (Chukar). Subacute dietary studies demonstrate that there is a range of toxicity from 24 ppm (bobwhite quail) to 712 ppm (mallard duck). Additional data are not required.

Avian dermal toxicity studies are not normally required. However, available data indicate that phosphamidon can be toxic to birds through contact with head, feet or through contact with sprayed foliage. Data indicate that small doses picked up from perches or applied to the feet of birds can be lethal. Doses in the range of 200 mg/kg or more caused effects in birds. Special tests are being required to determine the dermal toxicity of phosphamidon to birds. This special testing is being required for both technical phosphamidon, and an end-use formulation of the highest percent active ingredient.

Avian reproduction studies for phosphamidon are not available. Data are required to support uses of phosphamidon on crops with multiple applications such as cauliflower, cotton and apples. Therefore, an avian reproduction study with an upland species and a waterfowl species are required. Pending the results of these and/or other special studies on birds, special avian reproduction studies testing anticholinesterase effects of phosphamidon on bird parental behavior and bird productivity may be required.

There are no data available on the toxicity of degradates of phosphamidon to birds. Because delayed mortality is an indicated adverse effect of phosphamidon on birds, and because substantial reduction of populations of songbirds have occurred several weeks after phosphamidon applications to forests, it is possible that degradation products of phosphamidon can result in such effects. Therefore, these degradates must be identified and tested.

Aquatic Species

Acute toxicity tests with technical phosphamidon indicate that phosphamidon is highly toxic to fish. The 96-hour acute toxicity for rainbow trout is 7.8 ppm, and for the bluegill sunfish 3.4 ppm. Additional data are not required.

Acute toxicity tests with freshwater invertebrates indicate that phosphamidon is very highly acutely toxic to aquatic invertebrates. The acute toxicity values ranged from 0.012 ppb for Simocephalus (a daphnid species) to 15 ppb for Orconectes nais (crayfish). Additional data are not required.

There are no acceptable data evaluating the toxicity of technical phosphamidon to estuarine and marine organisms. Phosphamidon may reach estuarine environments from its use on citrus orchards. Since this use has the potential to result in significant concentrations of phosphamidon in estuarine waters and because the technical phosphamidon is demonstrated to be very highly toxic to aquatic invertebrates, aquatic organisms may be impacted. Acute studies on the toxicity of phosphamidon to estuarine and marine invertebrates are required.

Since aquatic invertebrate life-cycle data are not available, no conclusions can be drawn regarding the chronic effects of phosphamidon on aquatic invertebrates. An aquatic invertebrate life cycle study is required to support the agricultural use applications.

Wild Mammal Toxicity

There are no adequate data with which to assess the toxicity of phosphamidon to mammals. The only study available, which suggests a lethal dose of 18 mg/kg in the deer mouse, indicates that phosphamidon may be highly toxic to wild mammals. Although the Agency can draw no conclusions regarding the potential toxicity of phosphamidon to mammals, a wild mammal toxicity study is not being required at this time. However, if the acute mammalian studies required in the Toxicology Section indicate a rat acute toxicity ≤ 5 mg/kg, then a wild mammal toxicity study will be required.

Endangered Species

The Agency has evaluated the hazard posed by phosphamidon to endangered species based on jeopardy opinions prepared by the U.S. Department of the Interior's Office of Endangered Species (OES) for pesticides used on cotton, fruits, and vegetables. A number of listed bird and mammal species were identified as being jeopardized by the use of phosphamidon on cotton (refer to PR Notice 87-5 for labeling). Based on jeopardy opinions received for pesticides with similar use patterns, assumptions of jeopardy were made for various species of birds, mammals, aquatic invertebrates, insects and reptiles, and plants (based on loss of pollinators) by the use of phosphamidon on various fruits and vegetables. Should the Office of Endangered Species concur in this assumption of jeopardy, the Agency will specify that product labels include appropriate labeling. There were no endangered species impacted from the use of phosphamidon on sugarcane.

Non-target Insects

Data from honey bee acute contact toxicity studies indicate that phosphamidon is highly toxic to honey bees when bees are exposed to direct application or to dried residues on foliage. Precautionary labeling is specified for all phosphamidon products intended for outdoor applications. Additional data are not required.

There is sufficient information to indicate that phosphamidon, when used at standard field rates, is generally highly toxic to predaceous mites, parasitic wasps, and predaceous beetles. Study requirements for testing on predaceous and parasitic insects are currently reserved.

4. Product Chemistry

Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide consistent with new data requirements. Previously submitted data must be updated as appropriate.

E. TOLERANCE REASSESSMENT

Tolerances (expressed as phosphamidon) for residues of the insecticide phosphamidon (2-chloro-2-diethylcabamoyl-1-methylvinyl dimethyl phosphate) including all of its related cholinesterase-inhibiting compounds have been established in or on various raw agricultural commodities (40 CFR 180.239).

	Tolerances (ppm)			
Commodity	U.S.	Canadian[1]	Mexican[2]	MRLs International Codex[3]
Apples	1.0	--	1.0	0.5
Broccoli	0.5	--	0.5	0.2
Cantaloupe	0.25	--	0.25	--
Cauliflower	0.5	--	--	--
Citrus (Lemons, oranges, tangerines, grapefruit)	0.75	--	0.75	0.4
Cottonseed	0.1	--	0.1	--
Cucumbers	0.5	--	0.5	0.1
Peppers	0.5	--	0.5	--
Potatoes	0.1	--	0.1	0.05
Tomatoes	0.1	--	0.1	0.1
Sugarcane	0.1	--	0.1	--
Walnuts	0.1	--	0.1	--
Watermelon	0.25	--	0.25	0.1

---

[1] Canadian tolerances have not been established for residues of phosphamidon.

[2] Mexican tolerances are expressed in terms of phosphamidon *per se*.

[3] The Codex Maximum Residue Limits (MRL) are expressed as residues of phosphamidon and N-desethylphosphamidon (E- and Z-isomers of each).

Residue Data

The metabolism of phosphamidon in plants and animals is not adequately understood. Residues of [^{14}C] phosphamidon were identified and quantitatively determined only in immature bean plants. No edible livestock tissues (other than milk) were analyzed for residues, and residues were not characterized sufficiently in livestock. No poultry data were submitted.

The available plant metabolism data indicate that phosphamidon degrades rapidly when applied directly to the leaves of very young "two-leaf stage" bean plants. After 4 days, only 4 to 7 percent of the applied phosphamidon (approximately 15 ppm) was recovered. The predominant initial metabolite is the acetylcholinesterase-inhibitor, desethylphosphamidon, which is formed by enzymatic cleavage of an ethyl group. Desethylphosphamidon is subsequently rapidly metabolized in young bean plants.

The limited available ruminant metabolism data indicate that phosphamidon is degraded rapidly in animals, with most of the metabolic compounds being excreted in the urine. Phosphamidon is hydrolyzed at the phosphate-vinyl bond, forming dimethylphosphoric acid and alpha-chloroacetoacetic acid ethyl and diethyl amides. An additional pathway involves deethylation to form the N-unsubstituted amide of phosphamidon followed by reductive dehalogenation of this compound to form the dechlorinated, unsubstituted amide of phosphamidon.

Data gaps exist for plant and animal metabolism and storage stability. On receipt and review of the data required in these sections of the registration standard, the conclusions stated below regarding the adequacy of established tolerances are subject to change. Furthermore, since the data required for individual commodities are dependent on the metabolism data, the Agency recommends that metabolism data be obtained and submitted prior to any required residue data.

If the metabolism of phosphamidon in ruminants or poultry differs from that in rats, then data on the metabolism of phosphamidon in swine will also be required.

Available data support the established tolerances for residues of phosphamidon including all of its related cholinesterase-inhibiting compounds (as currently known) in or on the raw agricultural commodities (RACs) potatoes, tomatoes, cucumbers, cottonseed, and sugarcane. Note, however, that these tolerances, including the residue definition, will be reassessed upon receipt of the requested plant metabolism studies. Ultimately, the tolerance definition will be changed to list specific metabolites.

Insufficient data are available to evaluate the adequacy of the established tolerances for residues in or on broccoli, peppers, cantaloupe, watermelon, apples, oranges, and walnuts.

Although insufficient data are available to assess the established tolerances for residues of phosphamidon in or on cauliflower, grapefruit, lemons, and tangerines, no data are required for these commodities because data requested for crops listed in the previous paragraph will be translated to assess the tolerances. Translated data may not be used to support a crop group tolerance.

Processing studies are required for potatoes, oranges, apples, tomatoes, cottonseed, and sugarcane.

Insufficient data are available for residues of phosphamidon in (i) milk; (ii) fat, meat, and meat byproducts of cattle, goats, hogs, and sheep; or (iii) eggs, fat, meat, and meat byproducts of poultry. There are no established or proposed direct animal treatment uses for phosphamidon. Maximum livestock dietary intake figures were not calculated because there are numerous deficiencies in the residue data for the various feed items as well as animal and plant metabolism data. Upon receipt of these data, the need for, and the nature of the tolerances for phosphamidon residues in livestock will be reassessed; then the available data regarding magnitude of the residues in livestock will be evaluated as to its adequacy to support tolerances for residues in animal commodities.

No Canadian or Mexican tolerance or Codex maximum residue limit (MRL) exists for residues of phosphamidon in animal products. Therefore, no compatibility questions exist with respect to the Codex MRL.

The Codex MRLs and U.S. tolerances for phosphamidon residues in or on various commodities are expressed in different terms. A decision on revision of the U.S. tolerance definition is dependent upon additional plant and animal metabolism data.

Reports of regulatory incidents concerning phosphamidon have been received from the Food and Drug Administration (FDA); no illegal residues were detected in surveillance monitoring samples. Phosphamidon is not included in the United States Department of Agriculture's (USDA) National Residue Program.

Dietary Exposure

The No Observed Effect Level (NOEL) of 1 ppm (0.05 mg/kg/day) is based on the inhibition of serum and brain ChE activity from a 2-year feeding study in the rat. Because of the extensive residue chemistry and toxicology data gaps, the Agency cannot complete the dietary exposure reassessments. The tolerances and dietary exposure will be reassessed when the required data are submitted and evaluated.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions

Based on review and evaluation of all available data on phosphamidon, the Agency has made the following determinations·

1. No referral to Special Review is being made concerning the potential hazards to wildlife and aquatic organisms at this time.

Rationale: The Agency is concerned over the potential adverse impact of phosphamidon on birds, mammals and aquatic organisms resulting from the agricultural uses of phosphamidon. Available data indicate that phosphamidon is acutely to highly acutely toxic to various avian, mammalian and aquatic species. However, additional data on both technical phosphamidon and the degradate(s) are needed before the Agency can complete a full assessment of this concern. In the interim, as noted in this standard, the Agency is specifying precautionary label language to address this concern.

2. The Agency's position is that, in order for products to remain in compliance with FIFRA, product labels must contain language imposing a 48-hour reentry interval and requiring the use of protective clothing for all end-use products containing phosphamidon. Protective clothing and reentry statements are specified in Section IV.D.

Rationale: Phosphamidon is registered for use on a variety of agricultural sites all of which may involve hand labor, and may pose potential dermal exposure risks to workers. All phosphamidon products are currently classified in Toxicity Category I, bear a statement that they are rapidly absorbed through the skin, and are cholinesterase inhibitors. Current labeling does not provide a reentry interval and protective clothing is not specified. Both California and Texas have established reentry intervals of 14 days and 2 days, respectively. Foliar dissipation data for citrus and soil dissipation data for potatoes are currently under review in the Agency. After these data have been reviewed and evaluated, product specific reentry intervals for all agricultural uses will be determined. It is the Agency's position that a 48-hour interim reentry interval is required until these data have been evaluated and the Agency has announced any change in its position. Likewise, appropriate protective clothing is also needed to reduce exposure risks.

3. The Restricted Use classification for all uses of phosphamidon liquid formulations (75% and greater) and dust formulations (1.5% and greater) under FIFRA §162.31 will remain in effect. In addition, a statement identifying the reasons for the restriction are to appear on the label as specified in Section IV.D. It is the Agency's position that affected products must bear appropriate restricted use labeling in order to remain in compliance with FIFRA.

Rationale: All uses of phosphamidon, whether liquid or dust formulations, were classified for restricted use based on the acute dermal toxicity, and residue effects on avian and mammalian species. Although there are numerous toxicology and ecological effects data gaps, available data are sufficient to show that these effects are of continuing concern. In order that the public and/or the user be aware of the reasons for the restricted use classification, a statement identifying the reasons for the restriction are to appear on the label as specified in Section IV.D.

4. No tolerances or significant new food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure to phosphamidon.

Rationale: Available residue chemistry and toxicology data for phosphamidon are not sufficient to reassess existing tolerances. Plant and animal metabolism data and residue data on various commodities are required. The pertinent toxicology data requirements include: chronic feeding, oncogenicity, mutagenicity and metabolism (refer to Table A for specific residue chemistry and additional toxicology data requirements). Until these data are submitted and reviewed, the Agency cannot perform a tolerance reassessment.

5. In order to meet the statutory standard for continued registration, the Agency has determined that phosphamidon products must bear revised and updated labeling for hazards to nontarget organisms.

Rationale: Available data show that phosphamidon is highly toxic to birds, wild mammals, and toxic to aquatic organisms. Other data indicate that phosphamidon is moderately to highly toxic to the honey bee. Precautionary label statements relative to the potential risks posed by phosphamidon to nontarget organisms will provide useful information to promote practices to limit such exposure of nontarget species to this pesticide.

6. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.125 - Residue Chemistry

171-4 - Residue Analytical Method
171-4 - Nature of Residues (Metabolism)
171-4 - Magnitude of the Residues in Plants (field and processing studies on apples, oranges, potatoes and tomatoes)

§158.130 - Environmental Fate

161-1 - Hydrolysis
161-2 - Photodegradation - in water
161-3 - Photodegradation - in soil
161-4 - Photodegradation - in air
163-1 - Leaching and Adsorption/Desorption
163-2 - Volatility (Lab)

164-1 - Field Dissipation - Soil

165-1 - Confined Rotational Crop

§158.135 - Toxicology

81-1 - Acute Oral
81-2 - Acute Dermal
81-3 - Acute Inhalation
81-4 - Eye Irritation
81-5 - Dermal Irritation
81-6 - Dermal Sensitization
81-7 - Acute Delayed Neurotoxicity (Hen)

83-2 - Oncogenicity - mouse

85-1 - General Metabolism

§158.142 - Spray Drift

201-1 - Droplet Size Spectrum

202-1 - Drift Field Evaluation

§158.145 - Wildlife and Aquatic Organisms

71-1 - Avian Acute Oral (Degradate)
71-2 - Avian Subacute Dietary (Degradate)
71-4 - Avian Reproduction
71-5 - Field Testing (Mammals, Birds)
70-1 - Special Avian Testing (Dermal)

72-3 - Acute Toxicity to Estuarine and Marine Organisms
72-4 - Aquatic Invertebrate Life Cycle
70-1 - Special Testing - Aquatic Residue Monitoring

7. While the data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing phosphamidon may be sold, distributed, formulated and used subject to the terms and conditions specified in this Standard. The Agency has elected not to consider registration of any significant new uses while data gaps are being filled and data evaluated. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate [see FIFRA section 3(c)(2)(B) and 3(c)(7)]. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Criteria for Registration

To be registered or reregistered under this Standard, manufacturing-use and end-use products must contain phosphamidon as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To conform to this Standard, manufacturing-use and end-use products must contain phosphamidon. Each formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients present in the product, as well as impurities found at levels greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacturing-use or end-use products containing phosphamidon, provided the product is supported by appropriate acute toxicity data and the labeling for the product bears appropriate precautionary statements for the toxicity category in which the product is placed. Phosphamidon manufacturing-use and end-use products are currently in Toxicity Category I and the appropriate signal word is DANGER.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into other manufacturing-use products or into end-use products bearing federally registered uses. End-use products must bear federally registered uses. Appendix III (Use Index) lists all federally registered uses as well as approved maximum application rates and frequencies.

The use patterns currently registered for phosphamidon are as follows:

Terrestrial - Food Crop: apple; apple (nonbearing); broccoli; cantaloupe; cauliflower; cotton; cucumber; grapefruit; lemon; orange; peppers; potato; sugarcane; tangerine [1]; tomato; walnut; watermelon.

D. Labeling

All products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2, 83-3, 87-5, and below. Appendix II contains further information on label requirements.

In order to remain in compliance with FIFRA, pesticide products containing phosphamidon as the active ingredient may not be released for shipment by the registrant after January 31, 1989 unless the product bears amended labeling that complies with the specifications of this Standard.

In order to remain in compliance with FIFRA, pesticide products containing phosphamidon as the active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after January 31, 1990 unless the product bears amended labeling that complies with the specifications of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling of all manufacturing-use and end-use products .

Ingredient Statement

The ingredient statement for all phosphamidon products must list the active ingredient as:

ACTIVE INGREDIENT:
Phosphamidon: 2-chloro-3-(diethylamino)-
1-methyl-3-oxo-1-propenyl dimethyl
phosphate . . . . ___%

---

[1] This use is currently registered as a Special Local Need registration under 24(c) of FIFRA.

1. Manufacturing-Use Product Labeling

a. Use Pattern Statements

In order to remain in compliance with FIFRA, all manufacturing-use phosphamidon products must state that they are intended for formulation into other manufacturing-use or end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Appendix III. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

b. Environmental Hazards Statement

In order to remain in compliance with FIFRA, the following revised environmental hazard statement must appear on all manufacturing-use product labels:

> "This pesticide is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water board or Regional Office of the Environmental Protection Agency."

c. Protective Clothing, Equipment and Work Safety Statements

In order to remain in compliance with FIFRA, the following protective clothing, equipment and work safety statements must appear on all manufacturing-use product labels:

> "USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, OR DISPOSAL OF THE PESTICIDE: Protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical-resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots). In addition, mixer/loaders must wear a chemical-resistant apron. During equipment repair and cleaning, the protective suit need not be worn.
>
> IMPORTANT: If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear only clean clothes when leaving job -- do not wear contaminated clothing. Personal and protective clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Protective clothing and equipment that becomes heavily contaminated or drenched must be destroyed according to State and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE DECONTAMINATED."

2. End-Use Product Labeling

In order to remain in compliance with FIFRA, all end-use products containing phosphamidon as an active ingredient, must bear the following labeling statements:

a. Restricted Use Statement

In order to remain in compliance with FIFRA, the following statement must appear on the front panel of all end-use products containing phosphamidon:

"RESTRICTED USE PESTICIDE

Due to Acute Dermal Toxicity to Humans
and
Residue Effects on Avian and Mammalian Species

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

b. Environmental Hazards Statements

In order to remain in compliance with FIFRA, the following environmental hazard statement must appear on the label of all end-use products:

"This pesticide is toxic to aquatic invertebrates and wildlife. Do not apply directly to water or wetlands (including swamps, marshes, bogs, and potholes). Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water by cleaning of equipment or disposal of wastes."

c. Protective Clothing, Equipment and Work Safety Statements

In order to remain in compliance with FIFRA, the following protective clothing, equipment and work safety statements must appear on the labeling of all end-use products containing phosphamidon:

> "USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, DISPOSAL OF THE PESTICIDE, AND EARLY REENTRY INTO TREATED AREAS: Protective suit of one or two pieces covering all parts of the body except head, hand, and feet: chemical-resistant gloves; chemical-resistant boots). In addition, mixer/ loaders must wear a chemical-resistant apron. During equipment repair and cleaning, the protective suit need not be worn. If overhead exposure is likely, such as when flagging during aerial application, a hood or wide-brimmed hat must be worn.
>
> (The following label statement concerning application using an enclosed cab or cockpit is optional:
>
> IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeved shirt and longlegged pants; shoes and socks. Chemical-resistant gloves must be available in the cab or cockpit and must be worn during entry to and exit from the application vehicle. All other protective clothing and equipment required for use during application must be available in the cab and must be worn when exiting the cab into treated areas. When used for this purpose, contaminated clothing may not be brought back into the cab unless in an enclosure such as a plastic bag.)
>
> IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.
>
> AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear only clean clothes when leaving job -- do not wear contaminated clothing. Personal and protective clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal

clothing. Clean or launder protective clothing after each use. Protective clothing and equipment that becomes heavily contaminated or drenched must be destroyed according to State and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED."

d. Bee Precautionary Statements

In order to remain in compliance with FIFRA, the following bee precautionary statement must appear on the label of all end-use products containing phosphamidon:

> "This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this pesticide or allow it to drift to blooming crops or weeds if bees are visiting the treatment areas."

e. Reentry Interval and Protective Clothing for Early Reentry Statements

In order to remain in compliance with FIFRA, the following statements must appear on the labeling of all end-use products containing phosphamidon:

Reentry Interval

> "Reentry into treated areas is prohibited for 48 hours after the end of application, unless the protective clothing specified on this label for early reentry is worn."

Protective Clothing for Early Reentry

> "FOR EARLY REENTRY INTO TREATED AREAS: Use protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical-resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots)."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

---

[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The labeling requirements specified for manufacturing-use products in Section IV.

3. The data requirements listed in Table A.

C. End-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C (if included).

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

---

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

D. End-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If not eligible for the formulator's exemption, the data requirements listed in Table A and Table C (if included).

3. If eligible for the formulator's exemption, the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

---

[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing-Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

   d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

---

[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Product Specific Data Report (EPA Form 8580-4).

d. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

b. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End-Use Products containing the subject pesticide as, sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

D. End-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division·

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

1. These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

2. In addition, within 9 months from receipt of this document, you must submit to the Product Manager, three copies of draft labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling must be submitted. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

F. Addresses

The required information must be submitted to the following address:

William H. Miller (PM 16)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Divison
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry						
Product Identity and Composition						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	1/	1/	Yes 4/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	1/	1/	Yes 5/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples.	TGAI	All	1/	1/	Yes 6/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	1/	1/	Yes 7/	6 Months
63-3 - Physical State	TGAI	All	1/	1/	Yes 7/	6 Months
63-4 - Odor	TGAI	All	1/	1/	Yes 7/	6 Months
63-5 - Melting Point	TGAI	All	1/	1/	Yes 7/,8/	6 Months
63-6 - Boiling Point	TGAI	All	1/	1/	Yes 7/,9/	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	1/	1/	Yes 7/	6 Months
63-8 - Solubility	TGAI or PAI	All	1/	1/	Yes 7/	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	1/	1/	Yes 7/	6 Months
63-10 - Dissociation Constant	TGAI or PAI	All	1/	1/	Yes 7/	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	1/	1/	Yes 7/,10/	6 Months
63-12 - pH	TGAI	All	1/	1/	Yes 7/,11/	6 Months
63-13 - Stability	TGAI	All	1/	1/	Yes 7/	6 Months
Other Requirements:						
64-1 - Submittal of Samples	TGAI, PAI	All	-	-	Reserved 3/	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.120 Product Chemistry Footnotes

1/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been imposed and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

3/ If samples are needed, the Agency will request them. If required, samples will be due within 6 months after notification of requirement by the Agency.

4/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

5/ A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

7/ Physiochemical characterisitics (color, physical state, odor, melting point, boiling point, specific gravity, pH, solubility, vapor pressure, dissociation constant, K_{OW}, ph, and stability), as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.120 Product Chemistry - Footnotes (cont'd)

8/ Data needed if the technical chemical is a solid at room temperature.

9/ Data needed if the technical chemical is a liquid at room temperature.

10/ Required if the technical chemical is organic and non-polar.

11/ Required if the test substance is dispersible with water.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry					
171-2 - Chemical Identity[3]/					
171-3 - Directions for Use		(See Index)		Yes[4]/	18 Months
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Partially	00056937, 00083464, 00101264, 00151145, 00136247, 00090389, 40299301	Yes[5]/	18 Months
- Livestock	PAIRA	Partially	00083474, 00083475, 00090332, 00151145, 40299501	Yes[6]/	18 Months
171-4 - Residue Analytical Method					
- Plant Residues	TGAI and Metabolites	Partially	00083482, 00090331, 00090388, 00101271,	Yes[7]/	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Residue Analytical Method (cont'd)					
- Plant Residues (cont'd)			00101284, 00101292, 00101302, 00101308, 00101310, 00101315, 00136262, 00155166		
- Animal Residues	TGAI and Metabolites	No		Reserved[8]/	--
171-4 - Storage Stability Data	PAI	Partially	00090332, 00101314	Yes[9]/[10]/	18 Months
171-4 - Magnitude of the Residue					
- Crop Field Trials					
- Root and Tuber Vegetables Group					
° Potatoes	EP	Partially	00090331, 00101271, 00101285, 00101306	Yes[11]/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue					
- Crop Field Trials (cont'd)					
- Brassica Leafy Vegetables Group					
° Broccoli	EP	Partially	00083482, 00101271	Yes[12]/	18 Months
° Cauliflower	EP	Partially	00101271	Yes[13]/	18 Months
- Fruiting Vegetables (Except Cucurbits) Group					
° Peppers	EP	Partially	00090331	Yes[14]/	18 Months
° Tomatoes	EP	Partially	00090331, 00101271	Yes[15]/	24 Months
- Cucurbit Vegetables Group					
° Cucumbers	EP	Yes	00090331, 00101271	No	--
° Melons	EP	Partially	00090331, 00101271	Yes[16]/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue					
- Crop Field Trials (cont'd)					
- Citrus Fruits Group					
° Grapefruit	EP	Partially	00090388, 00101271	Yes[17]	18 Months
° Lemons	EP	Partially	00101271, 00101302	Yes[17]	18 Months
° Oranges	EP	Partially	00083482, 00101271	Yes[18] Yes[19]	18 Months 24 Months
° Tangerines	EP	Partially	00101271	Yes[17]	18 Months
- Pome Fruits					
° Apples	EP	Partially	00083482, 00090389, 00101271	Yes[20] Yes[21]	18 Months 24 Months
- Tree Nuts					
° Walnuts	EP	No		Yes[22]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue					
- Crop Field Trials (cont'd)					
- Miscellaneous Commodities					
° Cottonseed	EP	Partially	00101319, 00101276	Yes[23]/	24 Months
° Sugarcane	EP	Partially	00101276	Yes[24]/	24 Months
° Meat/Milk/ Poultry/Eggs	EP	Partially	00101266	Reserved[25]/	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.125 Residue Chemistry - Footnotes

1/Test Substance: TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled; EP = End-Use Product.

2/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

3/Refer to Product Chemistry Data Requirement tables (A,B).

4/The maximum number of applications and/or seasonal application rate must be specified on the product labels for apple, broccoli, cauliflower, cantaloupe, cucumber, watermelon, grapefruit, lemon, orange, tangerine, pepper, potato, sugarcane, tomato, and walnut.

5/Data describing the distribution and metabolism of vinyl or carbonyl-labeled [^{14}C]phosphamidon in mature, foliar-treated apples, potatoes, and broccoli. Foliar application rates should be large enough to permit ^{14}C-residue identification in appropriate parts of the mature plants. Upon receipt of acceptable metabolism data and validated residue data, the tolerance definition will be changed to list specific metabolites. Representative samples from the above-described test must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

6/Studies on the metabolism of vinyl or carbonyl-labeled [^{14}C]phosphamidon in ruminants and poultry. Animals must be dosed for a minimum of 3 days at a level sufficient to make identification and quantification of residues possible. Milk and eggs must be collected for analysis twice daily during the dosing period, and animals must be sacrificed within 24 hours after administration of the final dose. The distribution and identity of residues must be determined in milk, liver, kidney, muscle, and fat of ruminants, and in eggs, liver, kidney, muscle, and fat of poultry. Samples from the requested animal metabolism studies must also be analyzed using current enforcement methods to determine the usefulness of these methods for analysis of animal commodities.

7/All residues of concern, as determined from the requested metabolism studies, must be subjected to FDA Multiresidue Protocols I, II, III, and IV as required at 40 CFR 158.125(b)(15). Protocols are available from NTIS under Order No. PB 203734/AS. If the requested data regarding the nature of the residue in plants reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

8/Should the required animal metabolism data indicate that registered uses may result in phosphamidon residues of concern in animal feed items, then analytical methods for residues in animal commodities suitable for data

§158.125 Residue Chemistry - Footnotes (cont'd)

collection and enforcement will be required. Footnote 7, regarding FDA Multiresidue Protocols, will apply to any metabolites of concern that are unique to livestock.

9/To support crop residue data, storage stability studies must be conducted on either weathered samples or fortified frozen samples of a least one representative crop from each crop grouping (40 CFR 180.34) on which registered uses of the active ingredient exist. Guidance on the conduct of these studies is provided in Subdivision O, Addendum 2 (NTIS No. PB86-248192). Analyses of each crop must be conducted over a time period that includes the time interval that the raw agricultural commodity is held in frozen storage prior to the crop residue analysis. To support residue data on processed commodities, fortified storage stability data are required for all processing studies submitted to the Agency. Analyses must be conducted over a time period that includes the frozen storage of the raw agricultural commodity prior to processing and each processed commodity prior to the residue analysis. One of the following two approaches must be taken:

a. Storage stability data using weathered samples. Data are required for crop samples field treated with a typical end-use product which are frozen immediately upon harvesting. The integrity of the samples must be maintained by freezing. The samples must be analyzed for the active ingredient and each metabolite of concern on the day they arrive at the analytical laboratory, and then stored frozen and analyzed periodically for the active ingredient and each metabolite of concern.

b. Storage stability data using fortified samples. Data are required on the active ingredient and metabolites in which a group of untreated samples of raw agricultural commodities and processed crops are fortified (spiked) with the pure active ingredient and other groups are fortified individually with each additional metabolite. Immediately after fortification, the samples fortified with the active ingredient must be analyzed and samples fortified with other metabolites must be analyzed for only the metabolite with which the sample was fortified. Sample integrity must be maintained by freezing, and analyses for active ingredient and metabolites must be conducted periodically.

10/Storage intervals and conditions must be reported for the samples used to generate residue data submitted in support of the established tolerances (i.e., data reviewed as part of this Registration Standard) for phosphamidon residues in or on plant commodities. Data must also be provided which depict the decline in residues during the storage intervals and under the conditions reported if different from the above (see Footnote 9). In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field-weathered samples are used, the test substance must be a typical end-use product.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.125 Residue Chemistry - Footnotes (cont'd)

11/Residues must be determined in granules, chips, wet peel, and dry peel processed from potatoes bearing weathered residues. The fate of residues in baked whole potatoes, in baked and fried peeled potatoes and in dehydrated potatoes must be determined as well to ascertain effects of cooking on phosphamidon residues. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodity (RAC). If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

12/Data depicting phosphamidon residues of concern in or on broccoli harvested 3 days after the last of multiple foliar applications (with 10-14 day intervals) utilizing an SC/L formulation at 1 lb ai/A. Tests must be conducted in CA, which produced 92% of the 1984 U.S. broccoli crop (Agricultural Statistics 1985, p. 150).

13/The requested data for broccoli (refer to footnote 12) will be used to complete the data requirements for cauliflower.

14/Residue data reflecting multiple aerial and ground applications of the 8 lb/gal SC/L at 1 lb ai/A harvested 6 days posttreatment. Tests must be conducted in FL and TX. All residues of concern must be determined using validated methods.

15/Data depicting phosphamidon residues of concern in dry pomace, whole cooked tomatoes, puree, paste, catsup, and (raw and cooked) juice processed from tomatoes bearing measurable weathered residues. It may be necessary to use exaggerated rates to obtain measurable residues in or on the RAC. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

16/Determination of all residues of concern 1 day following the last of several foliar applications of the 8 lb/gal SC/L at 0.5 lb ai/A. Validated methods are to be used. Cantaloupes are to be treated in AZ, CA, and TX, and watermelon in FL.

17/The requested data for oranges (refer to footnote 18) will be used to complete the data requirements for grapefruit, lemons, and tangerines.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.125 Residue Chemistry - Footnotes (cont'd)

18/Depiction of residues of concern in or on oranges harvested 15 days after the last of multiple applications with aerial equipment of the 8 lb/gal SC/L formulation at 0.75 lb ai/A in 10 to 20 gal water/A. Tests must be conducted in CA (29%) and FL (69%); these States collectively account for ca. 98 percent of U.S. orange production (Agricultural Statistics 1985, p. 198).

19/All residues of concern must be determined in dried pulp, molasses, oil, and fresh and canned raw and cooked juice processed from oranges bearing measurable weathered residues. Exaggerated rates may be necessary to obtain measurable residues in the RAC. If residues concentrate in any processed product, then appropriate food/feed additive tolerances must be proposed.

20/Depiction of residues of concern of phosphamidon in or on apples harvested 30 days after the last of multiple foliar applications (at 7-day intervals) of the 8 lb/gal SC/L formulation with ground equipment at 2 lb ai/A in 800 gal of spray solution/A. Tests must be conducted in CA (6%), MI (9%), NY (12%), and WA (36%), States which collectively accounted for ca. 63 percent of U.S. 1984 apple production (Agricultural Statistics 1985, p. 242). Tests are also required depicting the same residues in or on apples 30 days after the last of multiple applications (at 14-day intervals) of the 8 lb/gal SC/L formulation with aerial equipment at 1.5 lb ai/A in 3 to 10 gal spray solution/A. These tests must be conducted in WA, the only State in which aerial applications are registered.

21/Depiction of residues of concern of phosphamidon in apple pomace, cooked apples (canned, including applesauce, and baked), dried apples, and fresh and canned raw and cooked apple juice processed from apples bearing measurable weathered residues. If residues in pomace or juice are found to occur at higher concentrations than in the RAC, then appropriate food/feed additive tolerances will be required.

22/Depiction of residues of concern of phosphamidon in or on walnuts 7 days after the last of multiple foliar applications of the 8 lb/gal SC/L formulation at 1 lb ai/A at 10-day intervals using ground equipment. Tests must be conducted in CA since this State produced virtually all of the 1982 U.S. English walnut crop (1982 Census of Agriculture, p. 368).

23/Depiction of residues of concern of phosphamidon in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues (exaggerated rates may be necessary to obtain such residues). If residue concentrations in any of these processed commodities exceed the residue concentration of the RAC, then the registrant must propose appropriate food/feed additive tolerances.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.125 Residue Chemistry - Footnotes (cont'd)

24/Data depicting residues in molasses and refined sugar processed from sugarcane treated at exaggerated rates. If residues are found to concentrate in these processed commodities, then the registrant must propose appropriate food/feed additive tolerances.

25/Should the requested animal metabolism studies indicate that residues of concern may occur in animal commodities as a result of registered uses, then tolerances will need to be proposed along with supporting residue data for edible tissues of ruminants and poultry.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for [3]/ Submission
§158.130 Environmental Fate						
Degradation Studies-Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A	No	-	Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A	No	-	Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No	-	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No	-	Yes[4]/	9 Months
Metabolism Studies-Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	No	-	No[5]/	--
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	No	-	No[5]/	--
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A	Partially	00153162	Yes[6]/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[3]
§158.130 Environmental Fate (cont'd)						
Mobility Studies (cont'd)						
163-2 - Volatility (Lab)	TEP	A	No	-	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	-	Reserved[7]	--
Dissipation Studies-Field						
164-1 - Soil	TEP	A	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A	No	-	No[5]	--
164-3 - Forestry	TEP	N/A	No	-	No[8]	--
164-4 - Combination and Tank Mixes	TEP	N/A	No	-	No[9]	--
165-5 - Soil, Long-Term	TEP	A	No	-	Reserved[10]	--
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved[11]	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[3]
§158.130 Environmental Fate (cont)						
Accumulation Studies (cont)						
65-3 - Irrigated Crops	TEP	N/A	No	-	No[12]	--
165-4 - In Fish	TGAI or PAIRA	A	No	-	Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	N/A	No	-	Reserved[13]	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.130 Environmental Fate - Footnotes

1/Composition: TGAI - Technical Grade of the Active Ingredient; PAIRA - Pure Active Ingredient, Radiolabeled; TEP - Typical End-Use Product.

2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, outdoor; I = Indoor; N/A = Not Applicable.

3/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

4/Required because of the highly toxic (Toxicity Category I, oral and dermal) nature of the chemical and the necessity to determine photoproduct toxicities and half-lives.

5/There are no aquatic uses currently registered for phosphamidon.

6/Data requirement partially satisfied; additional data required on mobility of unaged parent in two silt loam soils and aged parent in one clay soil.

7/Field volatility requirement conditional on results of the laboratory study--field volatility requirement reserved until acceptable laboratory data are received. If required, the study will be due within 15 months after notification of requirement by the Agency.

8/There are no forestry uses currently registered for phosphamidon.

9/Combination and tank mixes are not being addressed in this Standard.

10/Long-term field dissipation studies are conditional on results of the field dissipation study. The long-term field dissipation requirement is reserved until acceptable confined data are received. If required, the study will be due within 50 months after notification of requirement by the Agency.

11/Field crop rotation data are conditional on results of the confined study; the field crop rotation requirement is reserved until acceptable confined data are received. If required, the study will be due within 50 months after notification of requirement by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.130 Environmental Fate - Footnotes (cont'd)

12/This study is not required because the pesticide is not applied to or around water that is likely to be used for irrigation or other growing agricultural crops.

13/This study may be required if significant concentrations of the active ingredient and or/its degradates are likely to occur in aquatic environment and may accumulate in aquatic organisms. See foot note 15/ under § 158.145 data requirements. If required, the study will be due within 12 months after notification of requirement by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[3]/
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A	No	-	Yes	9 Months
81-2 - Acute Dermal	TGAI	A	No	-	Yes	9 Months
81-3 - Acute Inhalation - Rat	TGAI	A	No	-	Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A	No	-	Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	A	No	-	Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No	-	Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No	-	Yes	12 Months
Subchronic Testing						
82-1 - 90-Day Feeding -						
- Rodent	TGAI	A	No	-	No[4]/	--
- Nonrodent	TGAI	A	No	-	Yes	18 Months
82-2 - 21-Day Dermal	TGAI	A	No	-	Yes	12 Months
82-3 - 90-Day Dermal	TGAI	A	No	-	No[5]/	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for [3]/ Submission
§158.135 Toxicology (cont'd)						
Subchronic Testing (cont'd)						
82-4 - 90-Day Inhalation	TGAI	A	No	-	No[6]/	--
82-5 - 90-Day Neurotoxicity	TGAI	A	No	-	Reserved[7]/	--
Chronic Testing						
83-1 - Chronic Toxicity -						
- Rodent	TGAI	A	Yes	00157159	No	--
- Nonrodent	TGAI	A	No	-	Yes	50 Months
83-2 - Oncogenicity Study -						
- Rat	TGAI	A	Partially	00157159, 40299302	No[8]/	--
- Mouse	TGAI	A	No	-	Yes[9]/	50 Months
83-3 - Teratogenicity -						
- Rat	TGAI	A	Yes	00146424, 00146418, 00146419	No	--
- Rabbit	TGAI	A	Yes	00146422, 00146423	No	--
83-4 - Reproduction	TGAI	A	Yes	00146420	No	--
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A	No	-	Yes	9 Months
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for [3]/ Submission
§158.135 Toxicology (cont'd)						
Mutagenicity Testing (cont'd)						
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	-	Yes	9 Months
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A	No	-	Yes	24 Months
85-2 - Domestic Animal Safety	Choice	A	No	-	No[10]/	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.135 Toxicology - Footnotes

1/Composition: TGAI = Technical Grade Active Ingredient; PAI = Pure Active Ingredient, Radiolabeled; Choice = Choice of Several Test Substances Determined on a Case-by-Case Basis.

2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, Outdoor; I = Indoor; IP = Industrial Preservative.

3/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

4/A 2-year rat feeding study is available and a 90-day feeding study is therefore not required.

5/This study is not needed because the existing acceptable end-uses should not result in repeated human skin contact for extended periods.

6/This study is not required because the existing acceptable end-uses should not result in repeated inhalation exposure.

7/90-day neurotoxicity testing is reserved pending results of acute delayed neurotoxicity testing. If required, the study will be due within 15 months after notification of requirement by the Agency.

8/Historical control data requested for one study (MRID No. 00157159) are currently under review.

9/Only a National Cancer Institute bioassay is available, which is inadequate. Data for a full study must therefore be submitted no later than 50 months after the publication of this Standard.

10/Not required for this use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for[3/] Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	Yes	40270102	No[4/]	--
132-2 - Soil Dissipation	TEP	A	Yes	40270101	No[5/]	--
133-3 - Dermal Exposure	TEP	A	No	-	No[6/]	--
133-4 - Inhalation Exposure	TEP	A	No	-	No[7/]	--
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No	-	Yes[8/]	24 Months
201-1 - Drift Field Evaluation	TEP	A	No	-	Yes[8/]	24 Months

§158.140 Reentry Protection - Footnotes

1/Composition: TGAI - Technical Grade of the Active Ingredient; PAIRA - Pure Active Ingredient, Radiolabeled; TEP - Typical End-Use Product.

2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, outdoor; I = Indoor; N/A = Not Applicable.

3/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

4/For the agricultural crop use, a 48-hour interim reentry interval is established. Foliar dissipation studies have been received by the Agency and are under review.

5/For the agricultural crop use, a 48-hour interim reentry interval is established. Soil dissipation data are required for potatoes and peanuts. The Agency received a request for waiver of data and the waiver request has been granted for all crops except potatoes. The soil dissipation study was received by the Agency and is under review.

6/This study is not required due to current use patterns of phosphamidon. However, the registrant may submit this study at his option.

7/If the registrant submits the dermal exposure study, the inhalation study must be submitted along with the dermal exposure study.

§158.142 Spray Drift - Footnotes

8/Spray Drift Data Requirements: The Agency is requiring Droplet Spectrum and Spray Drift Evaluation tests due to the toxicity of the chemical, its methods of application (aerial and ground), and the likely exposure of off-site people and wildlife to the pesticide. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of phosphamidon for terrestrial food uses. The spray drift field evaluation is to be performed to reflect the application equipment, use pattern, and typical locations of use, which includes different weather factors, in the application of phosphamidon for the present uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for [3]/ Submission
§158.145 Wildlife and Aquatic Organisms						
Avian And Mammalian Testing						
71-1 - Avian Acute Oral Toxicity	TGAI	A	Yes	00160000	No	--
	Degradate	A	No		Yes[4]/	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Waterfowl	TGAI	A	Yes	00022923	No	--
	Degradate	A	No		Yes[4]/	9 Months
- Upland game bird	TGAI	A	Yes	00022923	No	--
	Degradate	A	No		Yes[4]/	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A	No	--	Reserved[5]/	--
	Degradate	A	No	--	Reserved[6]/	--
71-4 - Avian Reproduction						
- Waterfowl	TGAI	A	No	--	Yes[7]/	24 Months
	Degradate	A	No	--	Reserved[8]/	--
- Upland game bird	TGAI	A	No	--	Yes[7]/	24 Months
	Degradate	A	No	--	Reserved[8]/	--
71-5 - Simulated and Actual Field Testing - Mammals and Birds						
- Preliminary field study	TEP	A (Orchard Uses, Apple, Citrus)	No	--	Yes[9]/	24 Months
- Definitive field study	TEP	A (Orchard Uses, Apple, Citrus)	No	--	Reserved[9]/	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[3]
§158.145 Wildlife and Aquatic Organisms (cont'd)						
Avian And Mammalian Testing (cont'd)						
70-1 - Special Testing[10]						
- Dermal Toxicity						
- Upland Game Bird	TGAI	A	No	--	Yes[10a]	6 Months - (Acceptable Protocol)
	TEP	A	No	--	Yes[10b]	6 Months - (Acceptable Protocol)
	Major Degradate(s)	A	No	--	Yes[10c]	6 Months - (Acceptable Protocol)
- Outdoor (penned or nest box) reproduction study	TEP	A	No	--	Reserved[10d]	--
Aquatic Organisms Testing						
72-1 - Freshwater Fish Toxicity						
- Warmwater	TGAI	A	Yes	40094602	No	--
- Coldwater	TGAI	A	Yes	40094602	No	--

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for [3]/ Submission
§158.145 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing (cont'd)						
72-2 - Acute Toxicity to Fresh-water Invertebrates	TGAI	A	Yes	40094602	No	--
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	A	No	--	Yes[11]/	12 Months
72-4 - Fish and Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A	No	--	Yes[12]/	15 Months
72-5 - Fish Life Cycle	TGAI	A	No	--	No	--
72-6 - Aquatic Organism Accumulation	TGAI	A	No	--	Reserved[13]/	--
72-7 - Simulated or Actual Field Testing-Aquatic Organisms	TEP	A	No	--	Reserved[14]/	--
70-1 - Special Testing - Aquatic Residue Monitoring	TEP	A	No	--	Yes[15]/	6 Months-(Acceptable Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.145 Wildlife and Aquatic Organisms - Footnotes

1/TGAI = Technical Grade of the Active Ingredient; TEP - Typical End-Use Product; Degradate = Major Degradates of Phosphamidon as Determined by the Exposure Assessment Branch.

2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, outdoor; I = Indoor.

3/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

4/Required because a series of laboratory and field data indicated that delayed mortality of birds occurs after applications of phosphamidon (in some cases up to several weeks). Since the available information suggests that phosphamidon may have a relatively short half-life, it is possible that some degradate is toxic to birds. One oral acute toxicity study with either an upland species or a waterfowl, plus two subacute dietary toxicity studies, one with an upland species and one with a waterfowl, using each major degradate of phosphamidon must be performed.

5/If the mammalian studies required in Table A (Toxicology) indicate a rat acute oral toxicity $\leq$ 5 mg/kg, a wild mammal toxicity study will be required. If required, study will be due 24 months after notification of requirement by the Agency.

6/Reserved pending receipt of mammal acute toxicity data required in Table A (Toxicology) and avian toxicity data for degradates required under 71-1. If required, study will be due within 24 months after notification of requirement by the Agency.

7/Required because some uses of phosphamidon involve multiple applications.

8/Reserved pending receipt of avian acute and dietary toxicity studies with degradates. If required, study will be due within 24 months after notification of requirement by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.145 Wildlife and Aquatic Organisms - Footnotes (cont'd)

9/Terrestrial Field Studies

The use of phosphamidon for forestry has been determined to cause avian mortality and significant population reduction of birds. Certain adverse effects on mammals were also indicated as potentially possible. However, the available forestry field study data are inappropriate to simulate the exposure of nontarget organisms to orchard uses of phosphamidon. Therefore, additional field studies are required on orchard uses. The folloiwng information indicates the types of terrestrial field studies required for each use site. The types of terrestrial field studies are defined as follows:

a. Preliminary field study, which is a multisite, multilocation screening study to detect acute effects to mammals/birds. Multisite means several (8) treatment and sampling areas within each location. Location refers to geographically or ecologically distinct portions of the range where phosphamidon is applied for each particular use site (e.g., apple orchards or citrus orchards). The result of these preliminary screening studies will be used to determine the need for definitive avian/mammalian studies. The EEB has guidance for developing such studies. However, in the case of phosphamidon, the delayed response of birds/mammals requires additional guidance on the conduct of such studies. Protocols for conducting these field studies should be submitted to the Agency within 6 months of receipt of this Standard, for review and comment prior to the initiation of the study. A Guidance Document is available from the Agency, which outlines an acceptable approach to these studies. Consultation with the Agency is strongly advised prior to conducting such studies. If the terrestrial studies on the orchard uses of phosphamidon indicate a hazard to wildlife then the Agency is reserving the option to require other terrestrial field studies. If any of the orchard use patterns are cancelled, then preliminary field studies are still required for those use patterns where the estimated environmental concentration (EECs) exceed levels of the most sensitive species of mammalian and avian wildlife. The preliminary field study is due within 24 months after receipt of the Registration Standard.

b. Definitive field study, which is a multiyear, multilocation study to quantify the effects of the particular use on, in this case, exposed birds and possibly mammal species. This would involve studying several species with various censusing and population measuring techniques for several years to determine the extent of effects that have already been demonstrated in preliminary type studies and incident reports. This study is reserved pending results of the preliminary field study. The definitive field study will be required where the preliminary field study has identified potential field effects on populations of birds and mammals. A Guidance Document is available from the Agency, which outlines an acceptable approach to these studies. Consultation with the Agency is strongly advised prior to conducting such studies. The definitive field study will be due within 48 months after notification by the Agency that the study is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.145 Wildlife and Aquatic Organisms - Footnotes (cont'd)

9/Terrestrial Field Studies (cont'd)

Site Category	Use Site	Use	Type of Field Study Required
A	Terrestrial Food		
	Apples	Aphids and leafhoppers	Preliminary mammalian study. Definitive avian study.
	Citrus		
	FL	Aphids and thrips	Preliminary mammalian study. Definitive avian study.
	CA	Aphids and thrips	Preliminary mammalian study. Definitive avian study.
	AZ	Aphids and thrips (tangerines)	Preliminary mammalian study. Definitive avian study.

10/Because phosphamidon has been demonstrated to result in adverse effects on birds, including mortality (abrupt and delayed), illness (abrupt and delayed), abnormal behavior (singing and territorial occupation reduced), and because available data indicate that phosphamidon may have a relatively short half-life, it is possible that the parent compound or major degradate(s), or both, can be acutely toxic to, or could adversely affect the mating, nesting, or other nurturing behavior of parent birds. Effects on avian productivity could occur regardless of potential physiologic effects on oogenesis, spermatogenesis, fertilization, or development of eggs and young, which are typically studied by a Guidelines (71-4) avian reproduction study. Such a study would therefore be inadequate to investigate all of the potential effects of phosphamidon on avian productivity. The following studies are required as special tests:

a. Dermal toxicity study with upland game bird using TGAI; acceptable protocols must be submitted within 6 months of receipt of this Standard. The study is due within 12 months after notification by EPA that the protocol is acceptable.

b. Dermal toxicity study with upland game bird using TEP; acceptable protocols must be submitted within 6 months of receipt of this Standard. The study is due within 12 months after notification by EPA that the protocol is acceptable.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.145 Wildlife and Aquatic Organisms - Footnotes (cont'd)

10/(cont'd)

c. Dermal toxicity study with upland game bird using major degradate(s); acceptable protocols must be submitted within 6 months of receipt of this Standard. The study is due within 12 months after notification by EPA that the protocol is acceptable.

d. The following study is reserved pending results of the other special studies: Outdoor (penned or nest box) reproduction study of the potential effects of phosphamidon on parental birds and avian productivity, and which investigates mating, nesting, brood rearing, and productivity of waterfowl or passerine species, using TEP. If required, acceptable protocols must be submitted within 6 months after notification of requirement by the Agency. The due date for the study will be determined based upon the date of notification of the acceptability of the protocol by the Agency, and the complexity and scope of the study.

11/Required because use on citrus orchards has the potential to result in significant concentrations of phosphamidon in estuarine waters when used as directed, and because TGAI is demonstrated to be very highly toxic to aquatic invertebrates. Testing requirements are:

a. A 96-hour LC_{50} on a marine or estuarine shrimp species.

b. Either a 48-hour EC_{50} study on oyster embryolarvae or a 96-hour EC_{50} oystershell deposition study.

12/Life-cycle study of aquatic invertebrate is required.

13/Reserved pending receipt and evaluation of environmental chemistry and fate data required by EAB. If required, study will be due within 12 months after notification of requirement by the Agency.

14/Reserved pending receipt and evaluation of acute and life-cycle testing under this subpart, environmental chemistry and fate data requirement by EAB, and special testing for aquatic organisms required under 70-1. Concern is for toxicity to aquatic invertebrates, which through potential perturbations of aquatic food chains could result in adverse effects on finfish. If required, study will be due within 24 to 48 months after notification of requirement by the Agency. The specific due date and length of the study is determined by the scope and complexity of the study.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

§158.145 Wildlife and Aquatic Organisms - Footnotes (cont'd)

15/Aquatic residue monitoring data are required to determine the extent of exposure of aquatic organisms and to determine need for further testing requirements. Residue monitoring must be conducted in watersheds where apples have been treated with phosphamidon in these apple-producing regions: Pacific Northwest, North Central, and Eastern. At least five sampling sites (farm ponds) should be treated with PPD in each region. Water and hydrosoils (top 0.5 inch only) must be sampled, in duplicate, at 0, 1, 2, 4, and 8 days after treatment, and at 0, 1, 2, 4, and 8 days after the first major rainfall (1 inch or above). Acceptable protocols must be submitted within 6 months of receipt of this Standard. The study is due within 12 months after notification by the Agency that the protocol is acceptable.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSPHAMIDON

Data Requirement	Composition1/	Use Pattern2/	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission 3/
§158.155 Nontarget Insects						
141-1 - Honeybee Acute Contact Toxicity	TGAI	A	Yes	00036935	No	--
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	A	Yes	00037799, 00060625, 00060628	No	--
141-4 - Honeybee Subacute Feeding Study	Reserved 4/	-	-	--	-	--
141-5 - Field Testing for Pollinators	TEP	A	No	--	-	--

1/Composition: TGAI - Technical Grade of the Active Ingredient; PAIRA - Pure Active Ingredient, Radiolabeled; TEP - Typical End-Use Product.

2/The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, outdoor; I = Indoor; N/A = Not Applicable.

3/Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

4/Reserved pending development of test methodology.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSPHAMIDON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics						
63-2 - Color	MP	All	1/	1/	Yes	6 Months
63-3 - Physical State	MP	All	1/	1/	Yes	6 Months
63-4 - Odor	MP	All	1/	1/	Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	1/	1/	Yes	6 Months
63-12 - pH	MP	All	1/	1/	Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	1/	1/	Yes	6 Months
63-15 - Flammability	MP	All	1/	1/	Yes	6 Months
63-16 - Explodability	MP	All	1/	1/	Yes	6 Months
63-17 - Storage Stability	MP	All	1/	1/	Yes	15 Months
63-18 - Viscosity	MP	All	1/	1/	Yes	6 Months
63-19 - Miscibility	MP	All	1/	1/	Yes	6 Months
63-20 - Corrosion Characteristics	MP	All	1/	1/	Yes	15 Months

TABLE 3
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSPHAMIDON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	1/	1/	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	1/	1/	Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	1/	1/	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All	1/	1/	Yes	12 Months
62-2 - Certification of Ingredient Limits	MP	All	1/	1/	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	1/	1/	Yes	12 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSPHAMIDON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.120 Product Chemistry (cont'd)						
Other Requirements:						
64-1 - Submittal of Samples	MP	All	--	--	Reserved[3]	--

---

[1] Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[2] Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

[3] If samples are needed, the Agency will request them. If required, the samples will be due within 6 months after notification of requirement by the Agency.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSPHAMIDON

Data Requirement	Composition1/	Use Pattern	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for2/ Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	All	3/	-	Yes 4/	9 Months
81-2 - Acute Dermal	MP	All	3/	-	Yes 4/	9 Months
81-3 - Acute Inhalation - Rat	MP	All	3/	-	Yes 4/	9 Months
81-4 - Eye Irritation - Rabbit	MP	All	3/	-	Yes 4/	9 Months
81-5 - Dermal Irritation - Rabbit	MP	All	3/	-	Yes 4/	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	3/	-	Yes 4/	9 Months

---

1/ Composition: MP = Manufacturing-Use Product.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

3/ Although product specific toxicity data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product.

4/ If the MP is a technical grade active ingredient, refer to the Toxicology Table A for data requirements which may have been satisfied.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

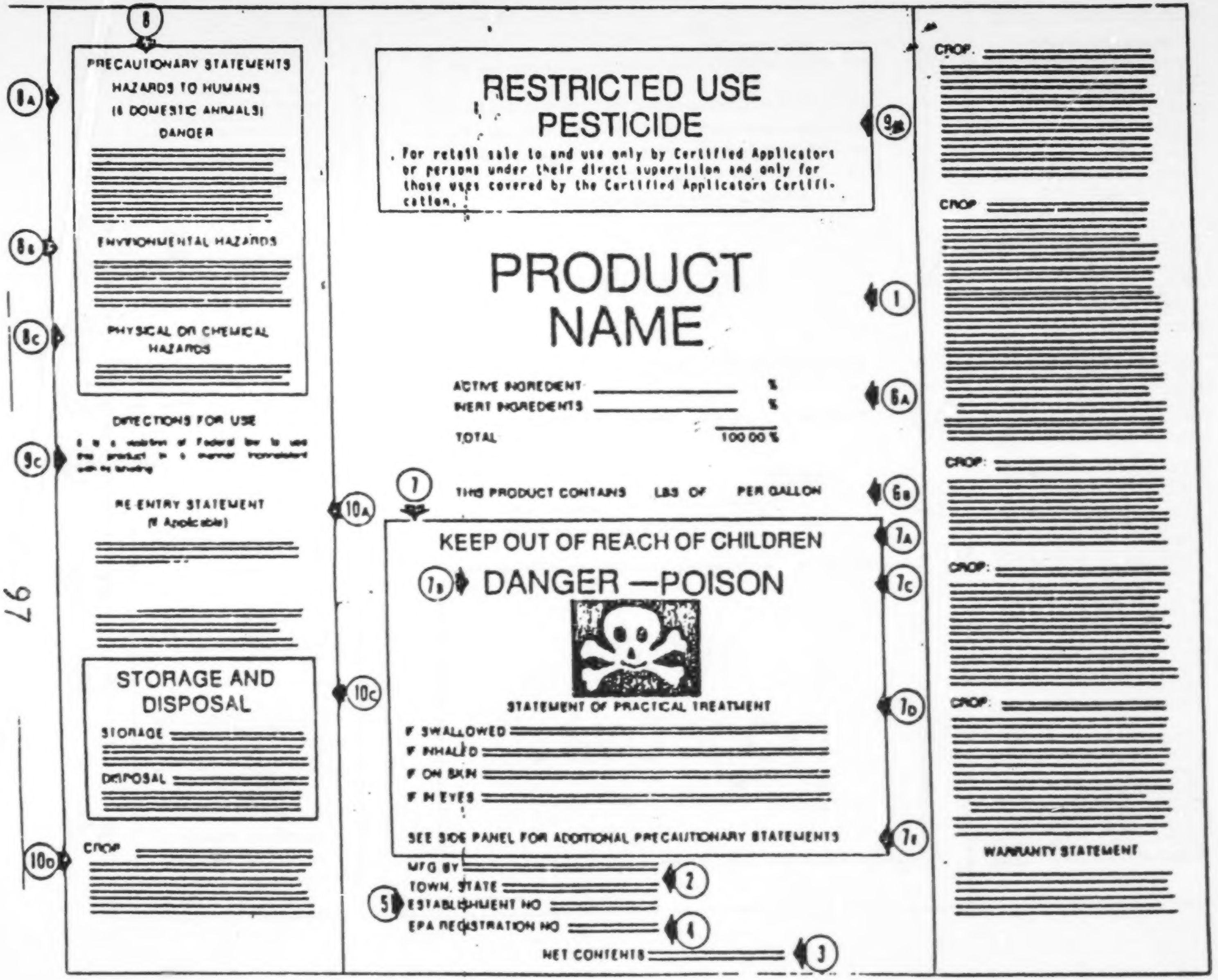
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.

PRODUCT NAME

ACTIVE INGREDIENT ____ %
INERT INGREDIENTS ____ %
TOTAL 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER — POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS

CROP:

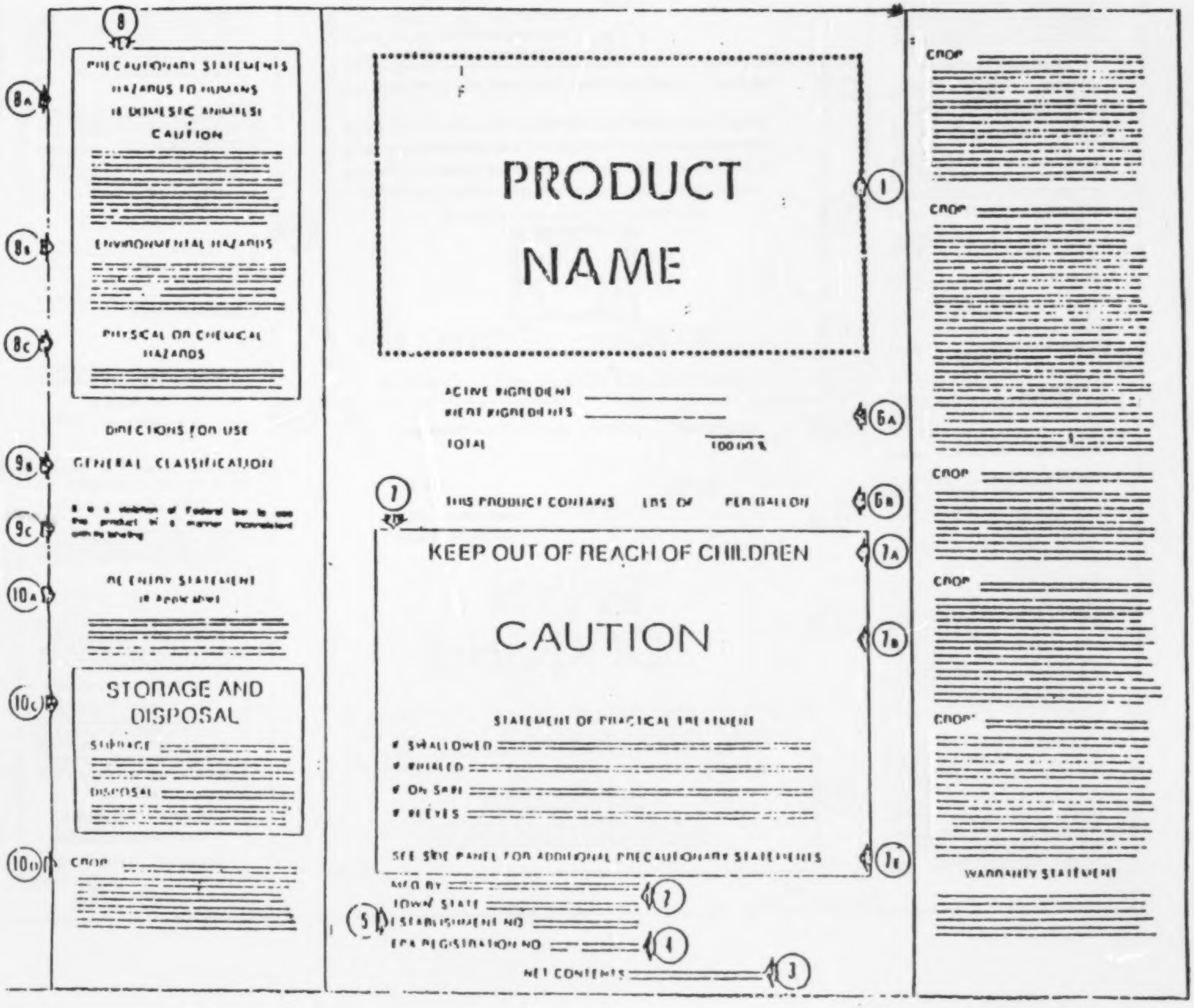
CROP

CROP:

CROP:

CROP:

WARRANTY STATEMENT


8
8A
8B
8C
9B
9C
10A
10C
10D
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
GENERAL CLASSIFICATION
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
RE-ENTRY STATEMENT
(If Applicable)
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
CROP
PRODUCT
NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00%
6A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
7
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7C
MFG BY
TOWN, STATE
2
ESTABLISHMENT NO
5
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

~~(e) *Conditional registration.* Any application for which a review of scientific data is needed, other than an application which the Agency determines may be considered for unconditional registration under paragraph (d) of this section, will be treated as an application for conditional registration under FIFRA sec. 3(c)(7) and will be reviewed and acted upon as set forth in §§ 162.160 through 162.177.~~

~~(f) *Denial of registration.* The Administrator shall deny an application reviewed under paragraph (d) of this section if any of the requirements of paragraph (d)(2) of this section are not met, or if there are insufficient data to make the required determinations.~~

~~(1) *Notification.* Promptly after making a determination to deny a registration, the Administrator shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.~~

~~(2) *Opportunity for remedy by applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.~~

~~(ii) The applicant may petition the Administrator to withdraw his application. The Administrator may, in his discretion, deny any petition for withdrawal and proceed to issue a notice of denial in accordance with paragraph (f)(3) of this section.~~

~~(3) FEDERAL REGISTER *publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly issue in the FEDERAL REGISTER a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.~~

~~(4) *Hearing rights.* Within 30 days following publication of the denial in the FEDERAL REGISTER, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of this chapter. If no hearing is timely requested, the denial shall become effective at the end of the 30 days.~~

~~(g) *Disposition of material submitted with the application.* The test data and other information submitted with an application shall become a part of the official file of the Agency for that application or registration. Except as provided by section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.~~

~~[48 FR 34004, July 26, 1983]~~

~~§ 162.8 Data to be furnished by applicant.~~

~~(a) An applicant for registration, reregistration, or amendment of a registration under FIFRA sec. 3(c)(5) shall furnish data as required by the Agency to determine whether his application may be approved under this Part.~~

~~(b) An applicant shall submit with his application any factual information regarding adverse effects of the pesticide on the environment or man that:~~

~~(1) Has been obtained by him or has come to his attention; and~~

~~(2) Insofar as he is aware, has not previously been submitted to the Agency.~~

~~Such information shall include, but shall not be limited to, published or unpublished laboratory studies and accident experience.~~

~~[48 FR 34005, July 26, 1983]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A

statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

~~(a)-(b) [Reserved]~~

~~(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.~~

~~(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:~~

~~(A) Has an acute dermal LD_{50} greater than 2,000 mg/kg;~~

~~(B) Has an inhalation LC_{50} greater than 2 mg/liter;~~

~~(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;~~

~~(D) Causes no more than moderate skin irritation within 72 hours;~~

~~(E) Has an acute oral LD_{50} greater than 1.5 g/kg for the formulation as diluted for use; and~~

~~(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).~~

~~(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:~~

~~(A) Has an acute dermal LD_{50} greater than 200 mg/kg;~~

~~(B) Has an acute dermal LD_{50} greater than 16 g/kg for the formulation as diluted for use as a mist or spray;~~

~~(C) Has an inhalation LD_{50} greater than 0.2 mg/liter;~~

~~(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days:~~

~~(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and~~

~~(F) Causes under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their their metabolite(s), or degradation product(s).~~

~~(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:~~

~~(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than $\frac{1}{5}$ the acute oral LD_{50}, measured in mammalian test animals as specified in the Registration Guidelines.~~

~~(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than $\frac{1}{5}$ the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.~~

~~(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $\frac{1}{10}$ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.~~

~~(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.~~

~~(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has sub-~~

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

---

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX APPENDIX

EPA Compendium of Acceptable Uses

PHOSPHAMIDON

TABLE OF CONTENTS

Site Name	Page
TERRESTRIAL FOOD CROP	2
(Agricultural Crops)	2
Apple	2
Apple (nonbearing)	3
Broccoli	4
Cantaloupe	4
Cauliflower	4
Cotton	5
Cucumber	4
Grapefruit	7
Lemon	7
Orange	7
Peppers	7
Potato	8
Sugarcane	8
Tangerine (AZ and CA only)	7
Tomato	8
Walnut	9
Watermelon	4

PHOSPHAMIDON*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:
Tech (89.5%)
SC/L (8 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: Phosphamidon is classified as a RESTRICTED USE PESTICIDE (due to acute dermal toxicity to humans and residue effects on avian and mammalian species). Phosphamidon has some endangered species restrictions. Refer to product labeling for use restrictions to protect endangered species.
Phosphamidon is toxic to aquatic invertebrates and highly toxic to wildlife. Harming or killing wildlife protected by wildlife conservation laws, such as the Migratory Bird Treaty Act or similar statutes, may result in civil penalties. Do not apply directly to water or wetlands (including swamps, marshes, bogs, and potholes). Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

Protective Clothing, Equipment and Work Safety: Use only when wearing the following protective clothing and equipment during mixing/loading, application, repair and cleaning of mixing, loading, and application equipment, disposal of the pesticide, and early reentry into treated areas: Protective suit of 1 or 2 pieces covering all parts of the body except head, hand, and feet; chemical-resistant gloves; chemical resistant boots. In addition, mixer/loaders must wear a chemical-resistant apron. During equipment repair and cleaning, the protective suit need not be worn. If overhead exposure is likely, such as when flagging during aerial application, a hood or wide-brimmed hat must be worn.

If application is performed using an enclosed cab or cockpit, the following protective clothing and equipment may be worn as an alternative: Long-sleeved shirt and long-legged pants; shoes and socks. Chemical-resistant gloves must be available in the cab or cockpit and must be worn during entry to and exit from the application vehicle. All other protective clothing and equipment required for use during application must be available in the cab and must be worn when exiting the cab into treated areas. When used for this purpose, contaminated clothing may not be brought back into the cab unless in an enclosure such as a plastic bag.

If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

After work: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear only clean clothes when leaving job--do not wear contaminated clothing. Personal clothing worn during work must be laundered separately from protective clothing and household articles. Store protective clothing separately from personal clothing. Clean or

---

*2-chloro-2-diethylcarbamoyl-1-methylvinyl dimethyl phosphate
2-chloro-N,N-diethyl-3-hydroxycrotonamide, ester with dimethyl phosphate
Dimecron

GENERAL WARNINGS AND LIMITATIONS (continued)

launder protective clothing after each use. Protective clothing and equipment that becomes heavily contaminated or drenched must be destroyed according to State and local regulations. Heavily contaminated or drenched clothing cannot be adequately decontaminated.

Reentry Interval: Reentry into treated areas is prohibited for 48 hours after the end of application, unless the protective clothing specified above for early reentry is worn.

Protective Clothing for Early Reentry: For early reentry into treated areas: Use protective suit of 1 or 2 pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical-resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots).

Bee Caution:
Phosphamidon is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply phosphamidon or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not allow phosphamidon sprays to drift on to maple trees, peaches, plums, cherry as phytotoxicity may occur. Unless otherwise specified, apply phosphamidon in the following quantities of water per acre:

Ground Equipment	
Vegetable and Field Crops	30 to 250 gallons
Deciduous Fruit Crops	60 to 800 gallons
Young Fruit Plantings	minimum of 15 gallons
Aircraft (where specified)	
Field Crops	3 to 10 gallons
Orchard Crops	10 to 20 gallons

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04001AA	Apple		1 ppm 30 day preharvest interval through 2.0 pounds per acre for foliar application.
IRACAAA	Aphids	0.167 lb/100 gal water [up to 800 gal/A] (8 lb/gal SC/L)	Foliar application.

EPA Compendium of Acceptable Uses

PHOSPHAMIDON

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple (continued)		
ITBUCSA IRACCUA IRAFAAA IMAAAGA IRACBQA	Codling moth (first brood) Green peach aphid Leafhoppers Leafminers Rosy apple aphid	0.25 lb/100 gal water [up to 800 gal/A] (8 lb/gal SC/L)	Foliar application. For *codling moth*, apply at petal fall and every 10 to 14 days thereafter until control is achieved. For other pests apply as a preblossom cover spray and repeat at 7 to 10 day intervals (14 to 21 day intervals in western states).
ILAVASA INBUAGA IRACCUA IRACBQA IRAKBYA	European red mite Fruittree leafroller Green peach aphid Rosy apple aphid San Jose scale	0.25 lb/100 gal water [up to 800 gal/A] (8 lb/gal SC/L)	Early delayed-dormant application. For areas other than western states, combine 2 gallons of a heavy, 70 sec., oil with the spray mixture. For the western states, combine 1.5 gallons of a very heavy, 140 sec., oil with the spray mixture. Do not combine phosphamidon oil sprays with captan, folpet or sulfur.
IRACAUA IRAFAAA IRACBQA	Apple aphid Leafhoppers Rosy apple aphid	[SLN] 0.75-1.5 lb/A (8 lb/gal SC/L)	Use limited to WA in conjunction with SLN-WA-820047 and SLN-WA-820056. Foliar application. Apply only by aircraft in 3 to 10 gallons of water per acre. May be applied by either Becomist dispensers or standard boom applicators. Do not apply under slow drying conditions or to trees under high moisture stress. Apply at 14 to 21 day intervals as needed.
/04001DA	Apple (nonbearing)		1 ppm Do not apply to bearing apple trees.
IRACAUA IRAFAAA IRACBQA	Apple aphid Leafhoppers Rosy apple aphid	0.25 lb/100 gal water/A (8 lb/gal SC/L)	Foliar application to nonbearing trees. Do not apply to trees under moisture stress. Apply when pests first appear and repeat at 14 to 21 day intervals.

EPA Compendium of Acceptable Uses

PHOSPHAMIDON

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13005AA /13008AA	Broccoli Cauliflower		0.5 ppm 3 day preharvest interval through 1 pound per acre for foliar application.
IRACAAA ITBJAHA	Aphids Imported cabbageworm	0.5-1 lb/A (8 lb/gal SC/L)	Foliar application. For aphids, apply at 10 to 14 day intervals to prevent buildup of damaging populations.
/10002AA /10010AA /10008AA	Cantaloupe Cucumber Watermelon		0.25 ppm (cantaloupe, watermelon) 0.5 ppm (cucumber) 1 day preharvest interval through 0.5 pound per acre for foliar application (cantaloupe, watermelon). 3 day preharvest interval through 0.5 pound per acre for foliar application (cucumber).
IRACAAA IRAFAAA IMAAAGA	Aphids Leafhoppers Leafminers	0.25-0.5 lb/A (8 lb/gal SC/L)	Foliar application. For cucumber, apply in 100 gallons of water per acre.
/10002AA IQAMBDA ILAVAAA IMOAAAA	(Cantaloupe) Fleahoppers Spider mites Thrips	0.125-0.25 lb/A (8 lb/gal SC/L)	Foliar application.
	Cauliflower		See Broccoli cluster.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28007AA	Cotton		0.1 ppm (cottonseed) 30 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 3 applications per season. Do not allow livestock to graze treated fields. Use limited to AZ, AR, CA, FL, KY, MS, NC, TN, and VA. The use of phosphamidon on cotton after February 1, 1988 has some endangered species restrictions. Before using phosphamidon in the counties listed below, the applicator must obtain the Pesticide Use Bulletin for Protection of Endangered Species for the county in which phosphamidon is to be used. The bulletin is available from your County Extension Agent, State Fish and Game Office, or the applicator's pesticide dealer. Use of phosphamidon in a manner inconsistent with the Pesticide Use Bulletin for Protection of Endangered Species is a violation of Federal laws: Alabama - Colbert, Green, Jackson, Lamar, Lauderdale, Limestone, Madison, Marshall, Morgan, Pickens, and Sumter Arkansas - Clay, Clark, Cross, Lawrence, Lee, Poinsette, Randolph, Sharp, and St. Francis California - Butte, Colusa, Glenn, Kern, Merced, Sacramento, Solano, Sutter, Tehema, and Yolo Florida - Broward, Dade, Glades, and Palm Beach Kentucky - Ballard, Butler, Edmundson, Green, Hart, Jackson, Laurel, Livingston, Marshall, McCracken, McCreary, Pulaski, Rockcastle, Taylor, Warren, and Wayne Mississippi - Itawamba, Lowndes, Monroe, and Noxubee

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
			North Carolina - Edgecombe, Nash, and Pitt Tennessee - Bedford, Blount, Claiborne, Decatur, Franklin, Hancock, Hardin, Hickman, Knox, Lincoln, Loudon, Marshall, Maury, Meigs, Monroe, Rhea, Roane, Scott, Sequatchie, Smith, Sullivan, and Wayne Virginia - Lee, Russell, Scott, Smyth, Tazewell, Washington, and Wise
IRACAAA IQAMBDA ILAVAAA IMOAAAA	Aphids Fleahoppers Spider mites Thrips	0.188 lb/A (8 lb/gal SC/L)	Foliar application for early season control (2 to 10 leaf stage). Apply by ground equipment beginning at the second true leaf stage.
IRACAAA	Aphids	0.25 lb/A (8 lb/gal SC/L)	Foliar application for mid to late season control. Apply in 1 to 5 gallons of water per acre by aircraft or in sufficient water for thorough coverage by ground equipment.
INAMADA IRAFAAA IQAMARA	Flea beetles Leafhoppers Lygus bugs	0.5 lb/A (8 lb/gal SC/L)	
	Cucumber		See Cantaloupe cluster.

PHOSPHAMIDON

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02002AA /02004AA /02010AA /02008AA	Grapefruit Lemon Orange Tangerine (AZ and CA only)		0.75 ppm 15 day preharvest interval through 2.5 pounds per acre (ground equipment - concentrate sprays) or 0.75 pound per acre (aircraft) or 0.5 pound per 100 gallons of water (ground equipment - dilute sprays) (400 to 3,000 gallons per acre) for foliar application.
IRACAAA IMOAAAA	Aphids Thrips	0.25-0.5 lb/ 100 gal water [400-3,000 gal/A] [ground equipment - dilute sprays] or 1.25-2.5 lb/A [ground equipment - concentrate sprays] or 0.5-0.75 lb/A [in 10-20 gal water/A] [aircraft] (8 lb/gal SC/L)	Foliar application. Apply during periods of aphid and thrips attack on new flush growth and repeat as needed.
	Lemon		See Grapefruit cluster.
	Orange		See Grapefruit cluster.
/11003AA	Peppers		0.5 ppm 6 day preharvest interval through 1 pound per acre for foliar application.
IRACAAA IMAAAGA IRABAAA	Aphids Leafminers Whiteflies	0.5 lb/A (8 lb/gal SC/L)	Foliar application. Apply when pests first appear.
ITBMCCA	European corn borer	1 lb/A (8 lb/gal SC/L)	Foliar application. Apply when pest infestation is expected.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/14013AA	Potato		0.1 ppm 14 day preharvest interval through 1 pound per acre for foliar application.
IRACAAA INAMCFA INAMADA IRAFAAA IMAAAGA IQAQAAA	Aphids Colorado potato beetle Flea beetles Leafhoppers Leafminers Stinkbugs	0.5 lb/A (8 lb/gal SC/L)	Foliar application. Apply in 1 to 5 gallons of water per acre by aircraft or in sufficient water for thorough coverage by ground equipment. Apply prior to row closing or at first sign of leafmining and repeat at 10 to 12 day intervals as needed.
ITAMAPA	Potato tuberworm	0.5-1 lb/A (8 lb/gal SC/L)	Foliar application. Apply in 10 gallons of water per acre by aircraft or in sufficient water for thorough coverage by ground equipment. Apply prior to row closing and repeat at 10 to 12 day intervals as needed.
/25003AA	Sugarcane		0.1 ppm 90 day preharvest interval through 0.5 pound per acre for foliar application. Do not allow livestock to graze on treated immature sugarcane fields.
IRACDOA	Yellow sugarcane aphid	0.5 lb/A (8 lb/gal SC/L)	Use limited to FL and PR. Foliar application. Apply by aircraft in 4 gallons of water per acre.
	Tangerine		See Grapefruit cluster.
/11005AA	Tomato		0.1 ppm 10 day preharvest interval through 0.5 pound per acre for foliar application.
IRACAAA INAMCFA INAMADA IMAAAGA IQAQAAA IRABAAA	Aphids Colorado potato beetle Flea beetles Leafminers Stink bugs Whiteflies	0.5 lb/A (8 lb/gal SC/L)	Foliar application. Apply in 1 to 5 gallons of water per acre by aircraft or in sufficient water for thorough coverage by ground equipment.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/03009AA	Walnut		0.1 ppm 7 day preharvest interval through 1 pound per acre for foliar application.
IRACAAA ITBUCSA	Aphids Codling moth	1 lb/A (8 lb/gal SC/L)	Foliar application. Apply in 10 to 20 gallons of water per acre by aircraft or in 400 gallons of water per acre by ground equipment. For codling moth apply at petal fall and repeat at 10 to 14 day intervals as needed.
IOBMAMA	Walnut husk fly	1 lb/A (8 lb/gal SC/L)	Foliar application. Apply in 10 to 20 gallons of water per acre by aircraft or in 200 to 300 gallons of water per acre by ground equipment. Apply after first egg "stings" occur on husks.
	Watermelon		See Cantaloupe cluster.

EPA Compendium of Acceptable Uses

PHOSPHAMIDON

Listing of Registered Pesticide Products by Formulation

&089.5001 89.5% technical chemical
phosphamidon (018201)
000100-00545

&108.0015 8 lb/gal soluble concentrate/liquid
phosphamidon (018201)
000279-02114 000400-00386 001526-00431 002935-00359
007001-00104 010163-00045 011656-00010 034704-00091

9999999 State Label Registrations

AZ Reg. No.
010026-05672 011656-05738

CA Reg. No.
010993-05223 011017-08193 011159-07333 011656-05681
035296-05788

Special Local Need (24(C)) Registrations

SLN-WA-820047 SLN-WA-820056*
*cancellation in progress

IV. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosphamidon Standard

MRID **CITATION**

00022923 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California Dept. of Entomology. ?: UC, Cooperative Extension, Leaflet 2287; published study)

00037799 Johansen, C. 1961. Bee poisoning investigations, 1961. Report No. 8577. (Unpublished study received Mar 26, 1975 under 3125-EX-119; prepared by Washington State Univ., submitted by Mobay Chemical Corp., Kansas City, MO.; CDL: 094390-I)

00056937 Anliker, R.; Beriger, E.; Geiger, M.; et al. (1961) The Synthesis of Phosphamidon and Its Breakdown in Plants. A translation of: Ueber dic Synthese von Phosphamidon und Seinen Abbau in Pflanzen. (Unpublished study received Dec 15, 1964 under 201-157; prepared by Ciba, Ltd., Switzerland, submitted by Shell Chemical Co., Washington, D.C.; CDL:100375-O)

00060625 Johansen, C., and R. Hutt. 1962. Bee poisoning investigations, 1962. Report No. 10617. (Unpublished study received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., submitted by Chemagro Corp., Kansas City, MO.; CDL: 092011-E)

00060628 Johansen, C.A., and J. Eves. 1965. Bee poisoning investigations, 1965. Report No. G-1705; Report No. 17338. (Unpublished study, including letter dated Jun 12, 1973 from C.A. Johansen to A.D. Cohick, received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., Dept. of Entomology, submitted by Chemagro Corp., Kansas City MO.; CDL: 092011-I)

00083464 Anliker, R.; Beriger, E.; Geiger, M.; et al. (19??) The Synthesis of Phosphamidon and Its Breakdown in Plants. Basle, Switzerland: Ciba, Limited. A translation of: Uber die Synthese von Phosphamidon und seinen Abbau in Pflanzen. Helvita Chimica Acta XLIV(VI):1622-1645. (Also in unpublished submission, including German text, received Feb 23, 1961 under PP0300, submitted by California Chemical Co., Richmond, Calif.; CDL: 090339-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosphamidon Standard

MRID	CITATION
00083474	Graham, O.H. (1961) Letter sent to T. Walter Reed dated Dec 8, 1961 Phosphamidon residues in the muscle and fat of a calf. (U.S. Agricultural Research Service, Entomology Research Div., Livestock Insects Investigations; unpublished study; CDL: 090339-N)
00083475	Chamberlain, ?; Hamilton, ?; Hicks, ? (19??) Studies of Irradiation and Radioactive Insecticides on Flies and Other Anthropods Affecting Man and Animals: Studies on the Metabolism of C14-Labeled Phosphamidon Given Orally to a Steer. (Unpublished study received Feb 23, 1961 under PP0300; submitted by California Chemical Co., Richmond, Calif.; CDL:090339-O)
00083482	California Chemical Company (1961) Summary of Typical Phosphamidon Residue Data in This Petition. (Compilation; unpublished study received on unknown date under PP0300; CDL:090339-X)
00090331	California Chemical Company (1960) Phosphamidon: Results of Tests on the Amount of Residue Remaining Including a Description of the Analytical Method Used. Includes method RM-4 dated Aug 1959. (Compilation; unpublished study received Apr 18, 1962 under PP0300; CDL:090341-G)
00090332	California Chemical Company (1960) Phosphamidon: Milk Residue Study. (Compilation; unpublished study received Apr 18, 1962 under PP0300; CDL:090341-H)
00090388	California Chemical Company (1963) Summary: Phosphamidon. (Compilation; unpublished study received Feb 14, 1965 under 5G0438; CDL:090476-C)
00090389	Pack, D.E. (1964) The Appearance and Decay of gamma-Chlorophosphamidon in Crops Sprayed with Phosphamidon: File 721.101. (Unpublished study received Feb 14, 1965 under 5G0438; submitted by California Chemical Co., Richmond, Calif.; CDL:090476-D)
00101264	Ciba Ltd. (1964) Metabolism of Phosphamidon in Plants; Identification of Desmethylphosphamidon in Plant Extracts. (Unpublished study received Nov 1, 1966 under 7F0546; submitted by Chevron Chemical Co., Richmond, CA; CDL:090673-U)
00101266	Ciba Ltd. (19??) Phosphamidon in Tissues and Organs of Two Oxen Given a Diet Containing 20 ppm of Active Compound. (Unpublished study received Nov 1, 1966 under 7F0546; submitted by Chevron Chemical Co., Richmond, CA; CDL:090673-W)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosphamidon Standard

MRID	CITATION
00101271	Chevron Chemical Co. (1965) Summary: Phosphamidon Residue Tolerance Petition. (Compilation; unpublished study received Nov 1, 1966 under 7F0546; CDL:090674-A)
00101276	Chevron Chemical Co. (1969) Summary: Phosphamidon Residue Tolerance Petition. (Compilation; unpublished study received Apr 1, 1970 under 0F0974; CDL:091676-B)
00101284	California Chemical Co. (1964) Method for the Estimation of Desmethylphosphamidon Residues: Method RM-4D. (Unpublished study received Feb 23, 1965 under 5G0438; CDL:092727-F)
00101285	Ospenson, J. (1967) Desethyl Phosphamidon Residues: File No. 741.10. (Unpublished study received Apr 17, 1970 under 7F0546; submitted by Chevron Chemical Co., Richmond, CA; CDL: 092834-D)
00101292	California Spray Chemical Corp. (1961?) Analysis of Phosphamidon Residues. (Unpublished study received on unknown date under PP0300; CDL:098432-G)
00101302	Chevron Chemical Co. (1961) Residue Data for Phosphamidon in Lemons and Grapefruit. (Compilation; unpublished study received Dec 22, 1964 under 239-1865; CDL:101206-A)
00101306	Chevron Chemical Co. (1960) Residue Data for Phosphamidon in Potatoes. (Compilation; unpublished study received Mar 28, 1960 under unknown admin. no.; CDL:119573-B)
00101308	Chevron Chemical Co. (19??) The Analysis of Phosphamidon Residues. (Unpublished study received Mar 28, 1960 under unknown admin. no.; CDL:119574-A)
00101310	Univ. of Maryland (19??) Phosphamidon Residue Analysis Method. (Unpublished study received Mar 28, 1960 under unknown admin. no.; submitted by Chevron Chemical Co., Richmond, CA; CDL: 119574-C)
00101314	Anliker, R. (1959?) Degradation of Phosphamidon in Plants and Its Residues in Foods and Feeds. (Unpublished study received Mar 28, 1960 under unknown admin. no.; prepared by Ciba Ltd., submitted by Chevron Chemical Co., Richmond, CA; CDL:119575-C)
00101315	Chevron Chemical Co. (1964) Residue Data for Phosphamidon in Eggplant. (Compilation; unpublished study received Apr 22, 1964 under unknown admin. no.; CDL:119583-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosphamidon Standard

MRID	CITATION
00101319	Davis, D.; White, A. (1960) Spray Residue: Phosphamidon. (Unpublished study received Mar 12, 1962 under 239-1506; prepared in cooperation with Ciba, Ltd., Switz., submitted by Chevron Chemical Co., Richmond, CA; CDL:119650-A)
00136247	Anliker, R. (1962) Letter sent to L. Gardner dated May 17, 1962: Phosphamidon, cis-trans isomerism. (Unpublished study received Nov 1, 1966 under 7F0546; prepared by Ciba Ltd., Switz., submitted by Chevron Chemical Co., Richmond, CA; CDL:090673-S)
00136262	Chevron Chemical Co. (1963) Phosphamidon Metabolite Residue Study Summary. (Compilation; unpublished study received Apr 17, 1964 under unknown admin. no.; CDL:119578-A)
00146418	Holson, J. (1985) Teratology Study of Phosphamidon Technical in Rats: Project No. 283005. Unpublished study prepared by Science Applications, Inc. 274 p.
00146419	Holson, J. (1985) Teratology Study of Phosphamidon Technical in Rats: Project No. 284001. Unpublished study prepared by Science Applications, Inc. 300 p.
00146420	Holson, J. (1985) Two-generation Reproduction Study of Phosphamidon Technical in Albino Rats: Project No. 282016. Unpublished study prepared by Science Applications, Inc. 1256 p.
00146422	Holson, J. (1985) Teratology Study (Seg II) in Albino Rabbits with Phosphamidon: (Dose Range-Finding Study): Project No. 283006. Unpublished study prepared by Science Applications, Inc. 76 p.
00146423	Holson, J. (1985) Teratology Study (Seg II) in Albino Rabbits with Phosphamidon: Project No. 283007. Unpublished study prepared by Science Applications, Inc. 215 p.
00146424	Holson, J. (1985) Teratology Study (Seg II) in Albino Rats with Phosphamidon: (Dose Range-finding Study): Project No. 283004. Unpublished study prepared by Science Applications, Inc. 77 p.
00151145	Geissbuehler, H.; Voss, G.; Anliker, R. (1971) The metabolism of phosphamidon in plants and animals. Residue Review 37:39-60.
00153162	Warren, J.; Connor, S. (1985) Leaching Characteristics of Parent Phosphamidon: Final Report #32451. Unpublished study prepared by Analytical Bio-chemistry Laboratories, Inc. 37 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosphamidon Standard

MRID	CITATION
00155166	Westberg, G. (1985?) Determination of Phosphamidon Residues in Hops. [Method]. Unpublished study prepared by Morse Laboratories, Inc. 3 p.
00157159	Wingard, B. (1986) Twenty Four Month Combined Chronic Oral Toxicity and Oncogenicity in Rats Utilizing Phosphamidon: Final Report: Study No. 410/1056. Unpublished study prepared by American Biogenics Corp. 4731 p.
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C. 106 p.
40270101	Breslin, J. (1987) Phosphamidon 8E: Dislodgeable Residues on Potatoes (Leaves and Soil): Lab Study No. 108-253. Unpublished study prepared by Wildlife Intenational Ltd. 43 p.
40270102	Breslin, J. (1987) Phosphamidon 8E: Dissipation of Dislodgeable Residues on Citrus (Leaves and Soil): Lab Project ID: 108-254. Unpublished study prepared by Wildlife International Ltd. 40 p.
40299301	Menzer, R.; Ditman, L. (1963) Effect of environmental factors on phosphamidon degradation. Agricultural and Food Chemistry 11(2):170-173.
40299302	National Cancer Institute (1979) Bioassay of phosphamidon for possible carcinogenicity. U.S. Department of Health, Education, and Welfare v. 16:1-98. DHEW publication no. (NIH) 79-816.
40299501	Clemons, G. (1968) Oxidative Metabolism of Phosphamidon in Animals. Master of Science Thesis. Located in subject file. 2 p.

V. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________ Date ________________

Guidance Document for ________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ____________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ____________________________
(Signature)

Dated: ________________ ____________________________
(Typed)